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AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 1995

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Agriculture, Rural Development, Foo...

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BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS HOUSE OF REPRESENTATIVES ONE HUNDRED THIRD CONGRESS SECOND SESSION

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND
DRUG ADMINISTRATION, AND RELATED AGENCIES

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ROBERT B. FOSTER, TIMOTHY K. SANDERS, and CAROL MURPHY, *Staff Assistants*

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Human Nutrition Information Service	1027



JUL 19 1994

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AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION AND RELATED AGENCIES APPROPRIATIONS FOR 1995

WEDNESDAY, MARCH 16, 1994.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

WITNESSES

DAVID A. KESSLER, M.D., COMMISSIONER

JANE E. HENNEY, M.D., DEPUTY COMMISSIONER, OPERATIONS

CAROL R. SCHEMAN, DEPUTY COMMISSIONER, EXTERNAL AFFAIRS

MARY JO VEVERKA, DEPUTY COMMISSIONER, MANAGEMENT AND SYSTEMS

PHILIP R. LEE, M.D., ASSISTANT SECRETARY FOR HEALTH

DENNIS WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. DURBIN. Good morning. Welcome to this subcommittee of appropriations on Agriculture, Rural Development, and Food and Drug Administration.

This morning we are happy to have as our witnesses representatives from the Food and Drug Administration. In addition to the Commissioner, Dr. David Kessler, we have Dr. Phil Lee, Assistant Secretary for Health, and we are happy to have you. Dr. Lee, you are with us, I believe for the first time. Also appearing before this subcommittee: Jane Henney, the Deputy Commissioner for Operations; Carol Scheman, the Deputy Commissioner for External Affairs; Mary Jo Veverka, Deputy Commissioner for Management and Systems; and Dennis Williams, Deputy Assistant Secretary for Budget.

Thank you again for joining us. We have a statement for the record from Dr. Kessler but Dr. Lee is going to make the opening statement to get us started.

Please proceed.

Dr. LEE. Thank you very much, Mr. Chairman.

I just wanted to take a moment to briefly say how strongly both the Secretary and I are supportive of the Food and Drug Administration and Dr. Kessler's leadership. I want to illustrate a few examples of areas where FDA is playing a vital role with respect to priority programs in the Department.

First, with respect to the goals to provide immunization coverage for all American children, age appropriate, the FDA, of course, is playing a critical role reviewing new license applications for vac-

cines as quickly as possible, to ensure the safety and effectiveness of the vaccines and to monitor any adverse effects.

With respect to another priority, HIV and AIDS, the Secretary has established a National Task Force on AIDS Drug Development. This idea was Dr. Kessler's in the beginning. Working closely with leaders in the pharmaceutical industry and the National Institutes of Health, the Secretary has established a committee. I will chair the Task Force. Dr. Varmus, the Director of NIH, and Dr. Kessler both will be co-chairs of the committee. The Task Force was established to expedite the development of new therapies and remove barriers or obstacles for AIDS drug development.

Other recent developments include the breakthrough agreement with Russia negotiated by the FDA over about a year's period of time. This will not only provide new opportunities for U.S. companies to market in Russia but, of course, it affords the Russian people the protections that we are afforded by the high quality work that the Food and Drug Administration does in this area with respect to drugs, biologics, and vaccines. A very important development.

Another important development in terms of public health protection is the Seafood Hazard Analysis Critical Control Points Program which was developed and pioneered in the Food and Drug Administration. The proposed regulations were issued on January 28, 1994 and they are preventive controls to ensure safety of seafood through incorporating risk based, quality controls systems in the processing. A very different approach and one we think is of great importance.

With thanks to your help, we did have a waiver for the FTEs in the Food and Drug Administration so we can move forward more rapidly with the user fee developments with respect to prescription drugs and the Mammography Quality Standards Act, both very important. We will also be proposing user fees for medical devices and that is another very important area. Again, with strong leadership in the FDA in the device area, we have made excellent progress during recent months.

Again, I would like to close by complimenting Dr. Kessler and the leadership in the FDA. His ability to recruit outstanding scientists and very able managers, has revitalized FDA. With respect to implementing the Prescription Drug User Fee Act, he has been particularly successful. Resources are limited, the problems are formidable and they are doing an outstanding job. I appreciate the chance to be here and join Dr. Kessler and the senior staff of the FDA in this hearing.

Mr. DURBIN. Thank you very much for joining us.

Dr. Kessler, again, we are happy to have you and your able staff. We sometimes disagree but there is no disagreement when it comes to our belief that you have one of the best groups of people in Washington and maybe in the country working to help protect America's consumers when it comes to food and drugs being sold in the country.

We have your statement for the record which we will include in its entirety.

We have a lot of questions. If you would like to summarize your statement at this point, we will proceed from there.

COMMISSIONER'S OPENING REMARKS

Dr. KESSLER. Thank you very much, Mr. Chairman, and members of the Committee. It is a pleasure to appear before you as we present the 1995 Food and Drug Administration budget proposal.

Mr. Chairman, with your permission, I would like to just preface my remarks with two broad observations about the important concerns to this Commissioner and the Food and Drug Administration.

My first general point is that FDA is highly conscious of and fully committed to its crucial public health role and as promoters of public health we appreciate this nation's enormous investment in high technology, biotechnology, and medical research.

These investments in new medications and medical devices can make the difference between life and death and between comfort and suffering for millions of patients. The vibrant and competitive high technology sector therefore makes a major contribution to the health of America. When FDA is able to speed safe, effective, and innovative products from the laboratories to patients, everyone benefits.

The second major focus of all of us at FDA is the Agency's obligation to have an all-inclusive public health agenda. For example, we are concentrating on the advancement of women's health. Last year, FDA issued new guidelines for inclusion of women in clinical trials. Over the next year, we will work with local review boards and sponsors to ensure that these guidelines are effectively implemented.

In 1993, we also issued interim final rules which became final last month for the Mammography Quality Standards Act. We are committed to making sure that all mammograms performed in this country are performed by well trained, competent professionals using state-of-the-art equipment. The menace of breast cancer in America has to be and is being vigorously attacked.

To these accomplishments of last year I want to add that we have already started preparatory work for the new Office of Women's Health. It will not only coordinate the agency's women's health agenda, it will generate new ideas and explore new opportunities for action.

Women's health, Mr. Chairman, is getting top priority attention at the agency.

Turning to the 1995 budget request, it can be most accurately characterized as lean. It builds on FDA's performance of last year. Let me just briefly mention some highlights.

In newspaper headlines, 1993 was the year of the false reports of syringes in Diet Pepsi cans. That series of episodes put FDA's new Office of Criminal Investigations to a difficult test and the new office passed with flying colors.

In other areas of our jurisdiction, the achievements were equally important but less dramatic. For instance, 1993 was the year when we announced a new system of preventive controls to increase the safety of seafood. In the medical device area, we have made major strides in improving the quality, efficacy, and timeliness of device review. In addition, I have already mentioned the progress in implementing the Mammography Quality Standards Act.

We saw tremendous activity in our drugs and biologics arena. The agency approved 370 new generic drug and biological product applications. Two were of significant importance. One was the first drug in 20 years for cystic fibrosis, DNase, and another very important drug for multiple sclerosis, betaseron, were both approved.

Both the Center for Biologics and Drugs have been actively recruiting new medical and scientific reviewers as provided for in the Prescription Drug User Fee Act enacted just a year ago. We are well on track to meeting the program's interim goals of eliminating the backlog of drug and biologic applications.

Blood safety and immunization coverage of American children remain high priorities for the agency and for this administration. In addition, both the Center for Biologics and the Center for Drugs have launched new initiatives. In 1993, we announced that FDA would review the regulation of human tissues used in transplantation.

Last June, we launched a Medwatch program, a revamped adverse reporting system for drugs and biologics and it is already bringing some of the results we hoped for.

We have made important progress in international harmonization of drug regulatory requirements.

As Dr. Lee just mentioned, a few weeks ago the Administration announced a major agreement with Russia under which FDA approval for drugs will be accepted in the Russian Federation.

I can continue listing some of our work over the last year but to save time let me just turn specifically to our 1995 budget request.

It is for \$988 million, \$54 million more than in 1994. All of the additional monies are additive user fees. Our 1995 budget proposal requests the authority to collect an estimated \$79 million in drug and biologic user fees, an increase of about \$23 million over 1994.

With these expected resources, if they become available, we expect full-time equivalent employment for human drugs and biologics programs to increase by 319 in 1995.

We are also committed to review and act on an escalating percentage of both priority and standard applications. A most important item that we hope to be placed on the agenda this year is the extension of user fees to medical devices. This is a very high priority for the agency and the administration which has included \$24 million in medical device user fees in the President's Budget.

During the last few months, we have been working with our authorizing committees and with medical device industry representatives to consider several important issues: the need for program improvements financed by industry user fees, the principles underlying the collection of those user fees, performance goals for the FDA, FDA management initiatives to be undertaken, and a preferred fee structure concept. We are hopeful that authorizing legislation for such a program will be enacted soon.

I have already alluded to the Agency's obligation to be an effective and speedy gatekeeper for a large sector of the American industry. This is particularly true about the manufacturers of medical devices whose number is growing fast and whose entrepreneurship and innovative spirit are formidable.

We contribute to the success of these firms through high standards of regulatory oversight, but keeping up with the industry

rather than becoming its bottleneck requires an enormous amount of resources.

Our 1995 request also continues the implementation of the Mammography Quality Standards Act. We propose the collection of \$6.5 million in user fees to fund inspections designed to ensure the reliability of mammography equipment, facilities, and services nationwide.

In summary, Mr. Chairman, our 1995 request includes \$645 million in budget authority and \$343 million from user fees, \$79 million from the prescription drug industry, \$24 million from the proposed new user fees for medical devices, \$6.5 million from user fees already authorized by the Mammography Act, \$5 million from fees charged for certification, and Freedom of Information Services, \$228 million, which will reduce FDA's reliance on appropriated funds.

Mr. Chairman and members of the committee, thanks to your past support, we have been vigorously able to pursue our traditional functions of consumer protection and promotion of public health. The 1995 budget request would enable us not only to carry on but to continue improving the Agency's performance to the benefit of the Nation.

Thank you, Mr. Chairman.

[CLERK'S NOTES.—The Commissioner's statements appear on pages 171 through 182. The Explanatory Notes appear on pages 183 through 316.]

CONSUMER PROTECTION

Mr. DURBIN. Thank you, Dr. Kessler.

You made reference to the Diet Pepsi scare which we can all recall. I think that was a perfect example of not only how important your agency is but how much Americans have come to trust the Food and Drug Administration. For days, if not weeks, we heard about the scare that syringes were being found in cans of Diet Pepsi. It led the news every night. Another example would pop up in some other part of the country. The stock of that company was suffering, the sales were suffering as a result of all these reports.

The Food and Drug Administration moved in and I think very professionally and very quickly assured American consumers that this was a hoax. Once it was established that people were planting these for the publicity, it is amazing to me how quickly that scare disappeared. That says so much about what you are about and all the people that have joined you at this table and I congratulate you for that.

And now let us talk about your new responsibilities.

This subcommittee has an equally great responsibility in funding your agency and the U.S. Department of Agriculture. Through the work in this subcommittee, we try to assure every American that they will have a good food supply, wholesome food, safe drugs, and that substances that might be a danger to them and their families will be regulated and watched very closely.

TOBACCO

I want to speak for a moment about one substance which we are concerned about in this committee and that is tobacco.

It amazes me in one respect that tobacco is even considered an agricultural product. It is not a food, it is not a fiber, and it is not a naturally occurring product with any nutritional value. It is grown by farmers, I will concede, who make a profit from its sale. But it is hard to rationalize adding tobacco to a list of commodities that would include wheat, corn, fruits, and vegetables, all products which enrich our lives.

My first question is why is tobacco in the U.S. Department of Agriculture at all and the next obvious question is why is it not in the Food and Drug Administration?

Your agency, as you have said, is the leading consumer protection agency for the Federal Government. You are our nation's primary regulator of products ingested into the human body. Tobacco is a product which kills more Americans every year than any other substance.

Dr. Kessler, you and your agency spend millions of dollars and worry over ingredients and substances which cause a tiny fraction of the deaths and misery caused by tobacco. You regulate, you inspect, you enforce the production of food and drugs which at their worst do not approach the lethal level of tobacco.

Historically, the Food and Drug Administration has given the benefit of the doubt to the tobacco industry as to whether they should be subject to FDA regulation. Recent disclosures in letters which you have made public suggest that you are taking a second look at tobacco.

Now, why are you doing that at this time?

Dr. LEE. David, why don't you respond and then I would like to add a few additional comments about that, Mr. Chairman.

Mr. DURBIN. Sure.

NICOTINE

Dr. KESSLER. Mr. Chairman, the first point, if I can just digress for a moment, is really to acknowledge your leadership. Every time I get on a plane, I think every time every one of us gets on a plane in this country, whether it is a short hop or it is across this great land of ours, we have you to thank because we can sit there and we can breathe air that is clean. That is really a great thing, not only for the passengers, but for the employees of those airlines who work there every day. And when you think about their accumulated exposure, it is just an enormous thing that you have accomplished.

You are correct. There is no greater public health issue. The statistics that you have given are right on the money. Four hundred thousand deaths a year, greater than any other public health challenge. We are looking at the issue anew.

There are two reasons for that. One is that there is growing evidence over the last number of years that nicotine is a strongly addictive substance. The second major reason we are looking at it is that there is increasing evidence that companies may in fact control the amount of nicotine in those products.

Let me just review for a moment the definition of a drug. There are three parts of the definition of a drug but the one that is relevant in our analysis is the part of the definition which says that

a drug is an article except for food intended to affect the structure and function of the body.

That is the definition of a drug and our analysis of the facts is to determine the status of nicotine. Previously, when we looked at the issue, we were always looking at the issue of whether the cigarette was a drug. What we have focused on over the last several years at the agency is whether the nicotine in the cigarette is the drug and that analysis is proceeding.

Dr. Lee.

CIGARETTE INGREDIENTS

Dr. LEE. Let me just say a few words about other areas of concern which I know are of concern directly to you, Mr. Chairman, and that has to do with the ingredients in cigarettes.

The Comprehensive Smoking Education Act of 1984 required the tobacco companies to report ingredients. Now, by law those cannot be reported by brand, by company nor by amount. So we receive a report from the companies. We have now identified 700 different ingredients.

Mr. DURBIN. If I could interrupt you for a moment, so that people understand what we are talking about. The notion that people are smoking just tobacco leaves, which occur naturally in nature, I think, have been debunked by disclosures that tobacco companies manipulate the level of nicotine and add other ingredients for various reasons. And you are referring to these other undisclosed ingredients which consumers are not aware of when they buy the product.

Dr. LEE. That is correct.

Now, 13 of those ingredients are not on the list which is a Food and Drug Administration list of everything added to food in the U.S., the so-called EFUS list. That is in addition to those products and foods that are generally regarded as safe.

Five of those, in fact, are regulated by Federal law as hazardous substances, some by the Department of Transportation, the transportation of hazardous substances; some by EPA through the Superfund and some by the Department of Labor through the Occupational Health and Safety Administration. So we have a serious problem.

Our General Counsel's office recently referred to the Department of Justice information that we asked them to investigate regarding the possibility that the tobacco companies were in fact adding nicotine to cigarettes. That is, of course, a natural ingredient in the tobacco leaf but it can be extracted and added.

That information is currently in the hands of the Department of Justice. We have responded to your request and have provided you with information to the extent that we can. We cannot disclose any of this information with respect to any of the details publicly, it can only be disclosed to an authorized congressional committee. We have done that in response to your request.

This is an area of very great concern to us and now to the Department of Justice to investigate these problems.

Just a couple of other things.

We will be submitting to the Congress as authorized by the 1984 legislation, a report on these matters. CDC is in the process of pre-

paring the report. It will be coming to my office in the very near future. We will then submit the report to the Secretary for transmittal to the Congress.

CDC has been working very closely with FDA on nicotine and other ingredient issues. Earlier, CDC asked the National Institutes of Health, National Cancer Institute if they could determine through toxicological measures a better means of measuring the ingredients. That did not prove to be feasible. We feel that some other approaches need to be taken. First of all is discussions with the Department of Justice.

Let me just say a couple of words about—

Mr. DURBIN. Doctor, if I might interrupt you for a second?

Dr. LEE. Yes.

Mr. DURBIN. What you are telling us today is that you have called upon the Department of Justice to do an investigation as to whether the tobacco companies are in fact manipulating the level of nicotine in cigarettes?

Dr. LEE. Yes, sir.

Mr. DURBIN. And do you have any timeframe as to when that investigation is to be completed?

Dr. LEE. I do not but we can certainly inquire again of the department and ask if they can give us a time when discussions would be completed.

[CLERK'S NOTE.—Subsequent to the hearing Dr. Lee issued the following statement to clarify his testimony related to a Department of Justice investigation.]

[The information follows:]

The Comprehensive Smoking Education Act of 1984 requires that cigarette manufacturers submit annually to the Department of Health and Human Services a list of ingredients added to tobacco during the manufacture of cigarettes. Questions have arisen as to the full list of ingredients added to tobacco.

The Centers for Disease Control and Prevention has discussed this issue with the Department of Justice's Office of Consumer Litigation.

This should not be construed as a formal referral for action to the Department of Justice.

Mr. DURBIN. Well, the first thing I would like to send to the Department of Justice is yesterday's New York Times. The presidents of the two major tobacco companies rose in defense of their product, and said, and I am quoting William Campbell, president and chief executive of Philip Morris. He says in his letter to the New York Times, "Our manufacturing results in less nicotine in every cigarette we make than in raw unprocessed tobacco. Moreover, consumer taste preferences have led to products with lower tar and nicotine levels. As a result, the overall nicotine content in cigarettes has declined more than 50 percent in the last 40 years."

I think the statement that Mr. Campbell is making in his defense in fact is enough to convict him. They have with their processing the ability to set the level of the nicotine in the cigarette so that it does not occur in the tobacco product as it is dispensed to the consumer.

Going back to Dr. Kessler's earlier point, if we assume, as we can, that nicotine is an addictive drug, we now have a company selling a product where they are in fact manipulating the level of that drug delivered to consumers.

Having said that, Dr. Lee and Dr. Kessler, how can we escape our responsibility to regulate that product?

Dr. LEE. I think our first job is to determine if in fact that is what they are doing. That is the reason that we have made the request to the Department of Justice.

Mr. DURBIN. And if in fact we find that there is an attempt to manipulate the level of nicotine in cigarettes sold to American consumers, what then is our responsibility?

Dr. LEE. I think if we find that is to be the case certainly the Department of Justice would have to determine what they would do in terms of any prosecution under current law. We would then need to review with you what would be the appropriate policy response and what actions does Congress need to take, working with us, to determine what policies are necessary to regulate nicotine in cigarettes.

Mr. DURBIN. Would it not also call into question the regulation of nicotine in cigarettes in the manufacturing process but also the actual sale of the product, the advertising of the product, and how it is promoted?

Would that not also be our responsibility if we find that tobacco companies are in fact delivering this addictive drug at manipulated levels to American consumers?

Dr. LEE. Yes. I think you have identified those issues, Mr. Chairman. You have outlined the areas where Congress and the Administration need to examine the policies and determine whether those policies need to be changed. We would certainly be very willing to work very closely with you in that regard.

CIGARETTE SALES BAN

Mr. DURBIN. Dr. Kessler, in your letter that was recently disclosed, you broached the subject of banning the sale of cigarettes and you raised, I think, legitimate public policy concerns as to whether or not that can or should occur. I would like you to address that at this point.

Dr. KESSLER. Mr. Chairman, I stated the definition of a drug. If in fact the record supports that nicotine in cigarettes meets that definition, and there is jurisdiction under the Federal Food, Drug, and Cosmetic Act, then the drug provisions of the Act could apply. Those provisions would require that before marketing a drug that an application be submitted to the Agency showing that the drug is safe and effective for its intended use.

I am not sure that anybody could prove that nicotine in cigarettes is safe and effective. Therefore, it would not be approved as a new drug.

If that is the case, then what are the options left under the Act if it cannot be approved as a drug?

Mr. DURBIN. If I could interrupt you for a second.

Dr. KESSLER. Sure.

Mr. DURBIN. You presently regulate nicotine gum, nicotine patches, and other companies that are taking this addictive drug and selling it to consumers. This falls under your current jurisdiction. You review their products and monitor their sales. Is that not correct?

Dr. KESSLER. That is correct.

Mr. DURBIN. So if the same is found true of the tobacco companies, that they are in fact dispensing nicotine, you are suggesting then that FDA would play a role in regulating their product as well?

Dr. KESSLER. The issue is whether nicotine in cigarettes is a drug for the purposes of the Act. If that jurisdiction is determined the drug provisions of the Act would kick in.

That would require manufacturers to demonstrate that the drug is safe and effective for its intended conditions of use. I doubt very seriously, Mr. Chairman, that that burden could be met for that product. In fact, I am convinced that it could not be met.

Dr. LEE. Mr. Chairman, those products would also include, of course, smokeless tobacco or so-called chewing tobacco, not just cigarettes.

Mr. DURBIN. I am glad you brought that up. That should be included in our conversation.

Dr. LEE. I was just recently in Vancouver, Washington meeting with about 200 Indian tribes and Alaska native tribes and the problem of smokeless tobacco use among native Alaskan children is a very serious problem. I was just flabbergasted by the information that was provided to us by tribes from native Alaska villages with respect to the use of smokeless tobacco in children.

Mr. DURBIN. The average age for people to take up cigarettes in this country is 13. The average age for children to take up spit tobacco or smokeless tobacco is nine. That is what we are faced with. And I think we all know how addictive this spit tobacco becomes because there is more nicotine going directly into your system and young children have no idea of the addiction they are getting dragged into.

Dr. Kessler, where I started with this conversation was the fact that tobacco is a unique product in terms of public regulation. We now know the dangers of tobacco. We now have a responsibility to the American consumers and children to respond to this danger.

Today, 3,000 children in America will start smoking and those children are the recruits the tobacco company needs to replace folks who quit smoking and those who are dying.

I think it is time for us to throw off the blinders and wake up to reality. If we are truly going to protect the American consumer, we have got to take a much different public policy approach toward tobacco and regulate this product to protect consumers nationwide.

FTEs

Mr. DURBIN. Let's try to establish the basics of this request. Your end of year FTE rate will be about 9,693 and your rate for FY 95 will be the same. But to achieve the same rate of FTEs you will substantially change the mix between centers. Tell me how many FTEs will be lost from each losing center if your budget is approved as is? Give me the information based on end of year strength not the FY 94 average.

Dr. KESSLER. The President's budget request proposes a redirection of FTEs to address high priority areas such as the implementation of the Prescription Drug User Fee Act and the Mammography Quality Standard Act. Based on end-of-year strength, Foods will absorb 145 FTEs; Drugs will absorb 141 FTEs, Devices will ab-

sorb 65 FTEs; NCTR will absorb 14 FTEs; and Program Management will absorb 19 FTEs.

CURRENT SERVICES

Mr. DURBIN. In light of the Administration's food safety initiative how will you continue current services for the Center for Foods?

Dr. KESSLER. We are absorbing the costs of current services under the President's budget proposal, and reducing the programs accordingly. The foods programs are important but, in the context of overall discretionary budget caps, must absorb substantial reductions.

Mr. DURBIN. Excluding the drug and biologics side of your program which is paid for by prescription drug user fees, what is your cost to maintain all other activities at current services? What were the costs of the inflation that FDA is to absorb in 1995? Again base your answer on the FTE level of 9,693.

Dr. KESSLER. The 1995 President's Budget contains a current services estimate for FDA for about \$35 million over the FY 1994 operating level. This estimate is based on an FTE usage of 9,334 or what is expected to be utilized by FDA on an annual basis during the year. What complicates this current services calculation is that we intend to end fiscal year 1994 with an FTE level that reaches 9,693 in total. This is the reason why there has been some confusion over what is needed for current services in FY 1995.

Normally, when current services calculations are developed from one year to the next, these calculations are done on an annual average staff operating level. If we were to calculate FY 1995 current services needs based on an average FTE usage in FY 1994 of 9,693 the added current services estimate would be about \$47 million, but would have FDA operating at an annual FTE level of 162 FTEs about the President's Budget. However, under the President's Budget, FDA will be effecting a significant shift in FTE utilization during FY 1995. We will be going down 384 FTEs in our base program and going up 384 FTEs in prescription drug user fees, medical device reviews, and Mammography Quality Standards Act implementation, resulting in a total usage in FY 1995 of 9,693.

ATTRITION AND FURLOUGHS

Mr. DURBIN. Let's assume you get your budget as requested, how will you implement it if you have to absorb \$47 million recognizing that the prescription drug user fees are directed to a single purpose?

Dr. KESSLER. Absorption of the \$47 million will be a major challenge for us. The 384 FTEs that we would have to lose, as I have described, would result in savings of somewhere close to \$24 million.

The remaining \$23 million would have to come from non-pay items. Non-pay operating funds for our centers have been reduced by 5 percent for each of the past two years, so we are already constrained by significant reductions. We would virtually halt all acquisitions and purchases, except for emergencies, and eliminate or substantially reduce much of our contract work, including State contracts. We would not be operating on a business as usual basis anywhere in the Agency except in the activities supported by user

fees. Travel would also be sharply curtailed, both for inspections and for other activities. To the extent that the non-pay savings would fall short of the targeted \$23 million target, we might have to furlough to maintain the additional 162 people in medical devices, in order to operate within our appropriations.

Mr. DURBIN. How many people will you lose through attrition and how many days will you have to furlough personnel?

Dr. KESSLER. To achieve this reduction, I will put in place a hard hiring freeze, effective October 1, 1994, on all FDA programs other than the prescription drug user fee programs, medical device review, and Mammography Quality Standards Act implementation. This means that for all other FDA programs and activities comprising approximately 7,000 FTEs, we will not be able to replace any personnel losses occurring in FY 1995. If attrition occurs at an annual rate of 5 percent, which we believe is a reasonable estimate, then we will lose 350 FTEs, saving 175 FTEs between October 1, 1994 and September 30, 1995. However, since these people will be lost evenly over the fiscal year, they will only account for half that much in FTE savings, or 175 FTEs.

We will save another 209 FTEs to operate within the amount available in this budget proposal. We will probably offer early retirements as a further incentive to reduce employment, and we may consider buyouts, to the extent they are economically feasible. We will also allow transfer into growth areas. However, the principle growth will be in areas of clinical and technical specialization not available elsewhere in the Agency. We are monitoring current hiring of support staff and aggressively pursuing reinvention/automation and initiatives to achieve administrative efficiencies next year. We hope this will give us greater flexibility to redistribute support personnel to relieve some of the downsizing challenges.

Mr. DURBIN. Can you direct the reduction so that you don't impact critical areas?

Dr. KESSLER. With reductions of this magnitude, there is very little that can be done to control the actual personnel losses among centers and programs. Attrition occurs randomly throughout all programs, and there is very little we can do to direct the impact of it on our programs.

Mr. DURBIN. One of your proposals is to establish user fees for the medical device program. If you do not get this approved what funding level do you need to continue only a current service program?

Dr. KESSLER. The \$47 million needed to maintain current services in FY 1995 at the FY 1994 year-end level in the Agency includes \$18 million for the medical device program. Approximately \$12 million accounts for 162 additional FTEs on board in the medical device program by September 30. All of the increased FTEs paid from traditional appropriations, exclusive of user fees, are in support of the medical device program, including mammography. Added to the 1994 device program estimate of \$153.3 million, the current services level for the device program in 1995 would be \$171.3 million and 2,106 FTEs.

MEDICAL DEVICE USER FEES

Mr. DURBIN. We know that FDA has been negotiating with the medical device industry for some time on the user fee issue. At what stage are the negotiations?

Dr. KESSLER. FDA had several meetings with representatives of the medical device industry between October and December 1993. These discussions resulted in an agreement on the principles underlying collection and use of user fees; performance goals for FDA; the size of user fee funding and the program areas in which the funds will be used; FDA management initiatives to be undertaken; and a preferred fee structure concept.

Mr. DURBIN. Do you expect the authorizing committee to act soon?

Dr. KESSLER. FDA has briefed staff from key authorizing committees and, on March 15, FDA provided technical comments on legislation drafted by the House Committee on Energy and Commerce that would authorize the collection of device user fees.

Mr. DURBIN. When will the user fee legislation have to pass in order for you to approve rules and regulations and begin collections by the beginning of the fiscal year?

Dr. KESSLER. FDA is prepared to implement a device user fee program as soon as authorizing and appropriating legislation is passed. The legislation under consideration, as we understand it, would not require any regulations to initiate the program.

PRESCRIPTION DRUG USER FEE MODEL

Mr. DURBIN. The Prescription Drug User Fee Act is the model by which medical device legislation is being proposed. The Act sets standards for FDA to meet. Tell us exactly what those standards are and how successfully you are meeting them. Certainly the big question is "Are drug approvals happening faster?" Do you have any proof that the prescription drug Act has sped up the process?

Dr. KESSLER. With your permission, Mr. Chairman, I would like to submit for the record a copy of my letters of September 14 and 21, 1992, to the Chairman of the House Committee on Energy and Commerce. These letters specify the goals for the Prescription Drug User Fee Act and are incorporated into the House report on that legislation.

The implementation of this new statute has been a very demanding undertaking. It defined many old processes in new ways, and demanded that we make substantial adjustments in how the agency does business in order to accommodate the requirements of this Act.

Regarding the recruiting goal set out in the letters, we are on target. We have about 180 more FTEs on board now dedicated to the process for the review of human drugs than we had in 1992, before the passage of the Act. We are continuing to recruit aggressively, and our on-board staff dedicated to this process should exceed 350 by the end of this fiscal year.

Backlogs of overdue original new drug applications were reduced from 35 to 6 in our Center for Drug Evaluation and Research, and from 9 to 3 in our Center for Biologics Evaluation and Research, as of January 31, 1994.

The real impact of increased review staff on review times will take a while to show, as it cannot be measured until applications submitted each year have been acted upon. It also takes time to train new staff before they are fully productive in their work.

We do have every reason, however, to expect continued improvement consistent with the Prescription Drug User Fee Act goals.

[The information follows:]

SEP 14 1992

The Honorable John Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20015

The Honorable Norman Lent
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman and Ranking Member:

As you are aware, the Food and Drug Administration (FDA) has been working with representatives of the pharmaceutical and biological prescription drug industries, and staff of your Committee, to design a "user fee" proposal. Under this proposal, the additional revenues generated from fees paid by these industries would be dedicated for use in expediting the prescription drug review and approval process, in accordance with performance goals that have been developed by FDA in consultation with the industries. The Dingell/Waxman draft bill dated September 12, 1992, the "Prescription Drug User Fee Act of 1992," reflects the fee mechanisms developed in these discussions. The performance goals are specified below. I believe they represent a realistic projection of what FDA can accomplish, with industry cooperation, and the additional resources that would be provided by the bill.

The goals of the FDA Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) are summarized as follows:

Five-Year Goals (to be implemented by September 30, 1997)

1. Review and act on complete Product License Applications (PLAs), Establishment License Applications (ELAs), and New Drug Applications (NDAs) for priority applications within 6 months after submission date. (Major amendments received within 3 months of the action due date will extend the review timeframes by 3 months.)
2. Review and act on complete PLAs, ELAs, and NDAs for standard applications within 12 months after submission date. (Major amendments received within 3 months of the action due date will extend the review timeframes by 3 months.)
3. Review and act on priority amendments to PLAs or ELAs, and supplements to NDAs, within 6 months after submission date.
4. Review and act on amendments to PLAs or ELAs, and supplements to NDAs that do not require review of clinical data (e.g., manufacturing supplements/amendments), within 6 months after submission date.

Page 2 - The Honorables John Dingell and Norman Lent

5. Review and act on standard amendments to PLAs or ELAs, and supplements to NDAs that require review of clinical data (efficacy supplements/amendments), within 12 months after submission date.
6. Review and act on complete applications resubmitted following receipt of a non-approval letter within 6 months after the resubmission date.

The term "act on" is understood to mean the issuance of an action letter after the filing of an application. The action letter, if it is not an approval, or approvable letter, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

Interim Backlog Goals

1. Eliminate overdue backlog of NDAs within 24 months of initiation of user fee payments; that is, review and act on all NDAs on CDER's October 1, 1992, overdue list, within 24 months.
2. Eliminate overdue backlog of PLAs, ELAs, and amendments to PLAs within 24 months of initiation of user fee payments; that is, review and act on the backlog of all PLAs, ELAs, and PLA amendments in CDER on October 1, 1992, within 24 months.
3. Eliminate overdue backlogs of efficacy and manufacturing supplements to NDAs within 18 months of initiation of user fee payments; that is, review and act on all efficacy and manufacturing supplements to NDAs on CDER's October 1, 1992, overdue list, within 18 months.

Interim Application Goals

FY 1994	55 percent of NDA and PLA/ELA submissions received during FY 1994 are reviewed within 12 months.	✓
	55 percent of efficacy supplements/amendments received during FY 1994 are reviewed within 12 months.	
	55 percent of manufacturing supplements/amendments received during FY 1994 are reviewed within 6 months.	

Page 3 - The Honorables John Dingell and Norman Lent

55 percent of resubmitted applications received during FY 1994 are reviewed within 6 months.

FY 1995 Each of the 55 percent goals of FY 1994 is increased to 70 percent.

FY 1996 Each of the 55 percent goals of FY 1994 is increased to 80 percent.

FY 1997 90 percent of each of the 5-year goals is achieved.

FDA to provide annual performance reporting on achievement of goals starting November 30, 1994.

Additional Interim Goals

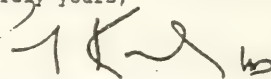
1. Fifty percent of FDA incremental review staff recruited and on-board by first quarter of FY 1995. Total staff increment on-board by end of FY 1997.
2. Establish an industry/FDA working group upon initiation of the user fee program to develop and oversee joint programs to improve review times.
3. Implement project management methodology for all NDA reviews within 12 months of initiation of user fee payments, and for all PLA/ELA reviews within 18 months.
4. Implement performance tracking and monthly monitoring of CBER performance within 6 months of initial user fee payments. (CDER already has such a program.)
5. Adopt uniform CANDAs standards during FY 1995.
6. Initiate a pilot CAPLAR program during FY 1993.

OMB has advised that there are no objections to the presentation of these views from the standpoint of the Administration's program.

Page 4 - The Honorables John Dingell and Norman Lent

We appreciate the support of you and your staffs, the assistance of other Members of the Committee, the Appropriations Committee, and the Ways and Means Committee in reporting a user fee proposal this session.

Sincerely yours,



David A. Kessler, M.D.
Commissioner of Food and Drugs

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Revised:MScheineson:9/14/92

Revised:SWallace:9/14/92

f/t:mjs:9/14/92

cc: HF-1

HF-40

HF-1

FDA Senior Staff



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration
Rockville, MD 20857

September 21, 1992

The Honorable John Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

The Honorable Norman Lent
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman and Ranking Member:

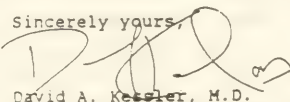
Following discussions among Committee staff, the Nonprescription Drug Manufacturers Association, and the Food and Drug Administration (FDA), I am supplementing my letter to you dated September 14, 1992, concerning the "Prescription Drug User Fee Act of 1992."

In my earlier letter, we identified five-year and interim performance goals relating to the review of New Drug Applications and supplements for prescription drugs. Several of these goals apply also to the review of applications and supplements for over-the-counter (OTC) drugs. Specifically, Five-Year Goals numbers 2, 5 and 6 apply to certain OTC drug review activities. These goals relate to the review, within 12 months, of standard New Drug Applications (NDAs) and supplements (and 6 months in the case of resubmitted applications). By their terms, they cover the review of NDAs for drugs initially marketed OTC, and the review of NDAs and supplements to switch a product from prescription to OTC status. The Interim Application Goals also apply to OTC drug products; however, the Interim Backlog Goals do not apply. As improvements in project management systems, review times, and application standards develop under the Additional Interim Goals, and as they affect OTCs, these improvements will also be applied to OTC drug products.

User fees from OTC applications will assist in funding the application review activities of the FDA Center for Drug Evaluation and Research and its Office of OTC Drug Evaluation. Both the FDA and the Nonprescription Drug Manufacturers Association have stated their express intent to study other methods of raising funds for the Office of OTC Drug Evaluation possibly through user fees on OTC drug establishments or on OTC drug products, or by some other means.

OMB has advised that there is no objection to the presentation of these views from the standpoint of the Administration's program.

Sincerely yours,


David A. Kessler, M.D.
Commissioner of Food and Drugs

MAMMOGRAPHY QUALITY STANDARDS ACT USER FEES

Mr. DURBIN. The budget request also proposes authority for user fees related to the Mammography Quality Standards Act. For the record please provide us with the authorization language.

Dr. KESSLER. I will be happy to provide that information for the record.

[The information follows:]

AUTHORIZING LANGUAGE FOR MQSA USER FEES

42 USC 263b(r)(1) (A) AND (B)

(r) FUNDING.—

(1) FEES.—

(A) IN GENERAL.—The Secretary shall, in accordance with this paragraph assess and collect fees from persons described in subsection (d)(1)(A) (other than persons who are governmental entities, as determined by the Secretary) to cover the costs of inspections conducted under subsection (g)(1) by the Secretary or a State acting under a delegation under subparagraph (A) of such subsection. Fees may be assessed and collected under this paragraph only in such manner as would result in an aggregate amount of fees collected during any fiscal year which equals the aggregate amount of costs for such fiscal year for inspections of facilities of such persons under subsection (g)(1). A person's liability for fees shall be reasonably based on the proportion of inspection costs which relate to such person.

(B) DEPOSIT AND APPROPRIATIONS.—

(i) DEPOSIT AND AVAILABILITY.—Fees collected under subparagraph (A) shall be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services as provided in appropriation Acts and shall remain available without fiscal year limitations.

(ii) APPROPRIATIONS.—Fees collected under subparagraph (A) shall be collected and available only to the extent provided in advance in appropriation Acts.

Mr. DURBIN. When will you publish rules and regulations on the collection process?

Dr. KESSLER. We anticipate publishing a notice in the Federal Register on or about October 1, 1994 that will state the fee schedule for inspections performed under the Mammography Quality Standards Act and explain our payment procedures.

Mr. DURBIN. Please describe in some detail the proposed collection process.

Dr. KESSLER. Mr. Chairman, our intentions with respect to collection procedures are still being discussed and formulated at this time. I will be glad to share with you our thinking, but there may be substantial changes between now and October 1.

At present, we envision a monthly billing cycle. For example, we would send out invoices in early to mid November for all inspections performed between October 1 and October 31. The invoice would require payment within 30 days or interest penalties would be assessed, as required under Federal statutes and regulations. We envision payments being sent to a bank or financial institution to expedite payment processing and crediting accounts. We also envision that the inspector will leave with the management of the inspected facility a brief statement about the billing and collecting process, so the facility will be reminded of the process at the time of the inspection.

MAMMOGRAPHY QUALITY STANDARDS ACT

Mr. DURBIN. What are the FY 94 resources being expended on the MQSA?

Dr. KESSLER. In 1994, FDA expects to spend at least \$13 million toward implementation of the Mammography Quality Inspections Act. This includes salary and benefits for the 65 employees who expect to hire for this work by the end of 1994, and purchase of equipment necessary for the State and Federal inspectors to use in the course of inspections. We will make a substantial investment this year in training contracts to assure that these new inspectors are well trained for this work, and we will enter into contracts with State governments under which they will do most of the inspections required under this Act.

Mr. DURBIN. What do you currently expect to spend in fiscal year 1995?

Dr. KESSLER. In FY 95, the budget proposes that we spend \$13 million. These funds will be spent on the same activities as in FY 94, although the spending mix will change somewhat within those activities. The \$6.5 million that the budget shows we intend to collect for inspections in FY 95 will be used to capitalize funding for future year mammography inspection activities.

Mr. DURBIN. The American Association of Radiologists has voluntary standards for mammography clinics. Are those standards suitable for your work? Will their use cut down on duplication?

Dr. KESSLER. The American College of Radiology's voluntary standards for mammography quality assurance and quality control have been used in the development of the interim regulations for MQSA. Their use certainly eliminated duplication of efforts by the FDA.

The legislative history of MQSA is clear in Congress' acknowledgement of the work ACR has done in mammography quality. We have built upon this experience and the experience of State mammography regulatory programs, as well as the experience of the Health Care Financing Administration in mammography quality regulations and inspections, in formulating regulations for MQSA. The goal of the MQSA regulations is to achieve uniform national standards that will improve the quality of the Nation's mammography.

MQSA AND WAIVERS

Mr. DURBIN. The proposed appropriations language includes a waiver of the provisions of Section 354(r) of the Public Health Service Act. What does this Section of the law do and why do you propose to waive it?

Dr. KESSLER. Section 354(r) of the Public Health Service Act requires that the costs of all inspections under the Mammography Quality Standards Act, for which charges are permitted, be paid from fees collected under that Act. The waiver requested in the appropriations act would allow FDA to pay for the costs of these inspections with appropriated funds in 1995, rather than from fees collected. The purpose is to allow FDA to capitalize this fund in 1995 with receipts collected, so there will be funds available in 1996 to begin paying these costs.

GENERAL USER FEES

Mr. DURBIN. Once again as it has over the past decade the budget proposes to establish a general user fee for purposes of deficit reduction. This time to the tune of \$228,000,000. Under this proposal exactly what industries would be charged, how much for each activity, and any other data. When will we see the details of this proposal? When will you be able to publish the details in the Federal Register?

Dr. KESSLER. There are many complex issues associated with collecting substantial new user fees. We do not yet have a detailed proposal to accomplish this.

I can assure you that we are still evaluating candidates for such fees. We are looking at virtually all FDA activities except those covered by specific current or proposed user fee authority. Activities left to consider include the food and animal drug activities of the Agency, our activities at the National Center for Toxicological Research, generic and over the counter drug programs, blood banks, most of our import and domestic inspection activities, and our enforcement and compliance activities. One of the first items we looked at was our import activities.

Because our plans have not been finalized, I am unable to advise you about how the fees will be levied on the regulated industry. One option is to have legislation that is self-executing.

Mr. DURBIN. What are the consequences to FDA if you do not get these user fees authorized and we give you what you asked for in appropriations?

Dr. KESSLER. If the Agency received only the \$585 million of appropriated funds requested and was unable to collect the \$228 million associated with new user fees, the results would be significant. As you know, about 65 percent of FDA's appropriation goes to pay for the salary and benefits of our 9,400 employees.

The President's budget clearly reflects a total salary and expense program level for FDA of \$997 million; less than that level would present a serious concern for FDA to continue to provide consumer protection.

BOARD OF TEA EXPERTS

Mr. DURBIN. For fiscal year 1994 Congress prohibited Federal funds from being used to operate the Board of Experts on Tea. In response to the Committee's action, the import tax was raised from 3.5 cents per hundredweight of imported tea to ten cents per hundredweight. This was done so that all Federal costs related to this program would be covered. The change to the import tax did not occur until after the appropriation process was complete. Can you describe for us how the Board is operating this year?

Dr. KESSLER. During 1994, the Tea Board is operating under a restriction that we may not use appropriated funds to pay expenses for the Board of Experts on Tea. However, we have separate statutory authority requiring that this Board exist and operate. As a result, we have made arrangements for all of the non-Federal members of the board to pay all of their own expenses related to operations of the Board.

BORDER INSPECTIONS

Mr. DURBIN. The Committee was approached last year by several members expressing dissatisfaction with the lack of personnel at border inspection stations along the Mexican border. According to your budget justification, you have added 5 staff for electronic entry review to the regions bordering Mexico. Where are these people located and how does the electronic review work?

Dr. KESSLER. FDA districts along the Mexican border are adding staff in Laredo, Houston, and El Paso in the Dallas District and in Nogales and Otay Mesa in the Los Angeles District.

The Electronic Entry Processing System—EEPS—is scheduled for implementation in Nogales and Otay Mesa on July 11 and July 25 respectively. Laredo, El Paso, and Dallas are scheduled for November 14, November 28, and December 12, respectively.

Mr. DURBIN. How will this speed up inspections?

Dr. KESSLER. Using selectivity criteria that reflect current Agency regulations and guidance, EEPS will speed up the initial review of FDA regulated entries. Entries of low public health concern and low regulatory significance can be allowed entry within 15 minutes with minimal involvement by FDA personnel. As a result, FDA inspectional resources will be directed to products that represent a high risk to public health and have a higher probability of failing to meet United States admissibility standards.

MILK FROM COWS TREATED WITH RECOMBINANT BOVINE
SOMATOTROPIN

Mr. DURBIN. On February 24th I wrote you about guidance for voluntary labeling of milk from cows treated with recombinant bovine somatotropin. How are you enforcing that guidance?

Dr. KESSLER. FDA published in the *Federal Register* of February 10, 1994 at 59 FR 6279 interim guidance on the voluntary labeling of milk and milk products from cows that have not been treated with recombinant bovine somatotropin. FDA stated in the notice that it viewed the document primarily as guidance to the States as they consider enforcement of FDA's interim guidance on voluntary rbST labeling claims. The Agency noted that given the traditional role of the States in overseeing milk production, FDA intended to rely primarily on the enforcement activities of the interested States to ensure that rbST labeling claims are truthful and not misleading. The Agency is available to provide assistance to the States.

However, if the Agency were to enforce rbST labeling claims, it would consider several factors to determine whether enforcement action is warranted. One of these considerations is whether a regulatory action against the alleged violations could be pursued successfully. This factor includes not only a consideration of whether FDA believes that the labeling is false or misleading under the misbranding provisions of the Food, Drug, and Cosmetic Act, but whether sufficient evidence can be presented to convince a court to act against the product. Another factor that we consider is the seriousness of the alleged violation in comparison with other violations that we confront on a daily basis.

Mr. DURBIN. What happens in cases of noncompliance?

Dr. KESSLER. In cases of noncompliance requiring FDA action, the Agency would issue a warning letter to the responsible firm. If the violation were not corrected, the Agency could initiate seizure, multiple seizure, or other court action under provisions of the Food, Drug, and Cosmetic Act.

Mr. DURBIN. Have any violations occurred to date?

Dr. KESSLER. FDA has not taken any enforcement action concerning false and misleading labeling relating to rbST to date.

Mr. DURBIN. What resources are you expending on monitoring of these provisions?

Dr. KESSLER. As discussed in the February 10, 1994 *Federal Register* notice, FDA is relying primarily on the enforcement activities of the interested States because of the traditional role of the States in overseeing milk production to ensure that rbST labeling claims are truthful and not misleading. FDA certainly opposes all false or misleading food labels, including those with misleading statements about rbST. However, FDA's responsibility extends to protecting the entire U.S. population from safety and labeling violations involving the large number of products that FDA regulates. The Agency's regulatory decisions must be based upon that broad public responsibility. Therefore, the Agency is relying fundamentally on monitoring activities of the interested States concerning rbST labeling claims and is prepared to provide guidance to the States as is necessary to support State enforcement action.

PREScription DRUG USER FEE ACT WAIVERS

Mr. DURBIN. The Prescription Drug User Fee Act allowed the Food and Drug Administration to waive fees for small businesses or for other reasons on a case-by-case analysis. Have you used that authority for any companies? Please explain the rules and regulations that govern the waiver authority.

Mr. KESSLER. I will be happy to provide a description for the record.

[The information follows:]

Waivers under the Prescription Drug User Fee Act

The Prescription Drug User Fee Act of 1992 directs FDA to grant a waiver of an application, product, or establishment fee if it finds:

(1) a waiver is necessary to protect the public health, 21 U.S.C. § 379h(d)(1);

(2) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances, 21 U.S.C. § 379h(d)(2);

(3) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the agency in conducting the process for the review of human drug applications for such person, 21 U.S.C. § 379h(d)(3);

(4) assessment of the fee for an application or a supplement filed under section 505(b)(1) of the act, 21 U.S.C. § 355(b)(1), pertaining to a drug containing an active ingredient would be inequitable because an application for a product containing the same active ingredient filed by another person under section 505(b)(2), 21 U.S.C. § 355(b)(2), of the act could not be assessed an application fee, 21 U.S.C. § 379h(d)(4); or

(5) the marketing application was withdrawn after filing and the agency performed no substantial work on the marketing application after it was filed, 21 U.S.C. § 379h(a)(1)(B)(ii)(II).

In addition, for small businesses with fewer than 500 employees that do not have a drug product introduced or delivered for introduction into interstate commerce, the User Fee Act directs FDA to defer assessment of application fees for one year after submission of a marketing application, and to reduce application fees by 50 percent. 21 U.S.C. § 379h(b)(2).

On July 16, 1993, along with the first user fee invoices, FDA sent to all companies subject to user fees and other interested persons the Draft Interim Guidance Document on Waivers of and Reductions In User Fees. FDA currently is preparing a notice of proposed rulemaking on standards and procedures for the submission to, and review by, FDA of requests for waivers or reductions of user fees.

FDA has used its authority under the User Fee Act to waive or reduce user fees for certain small businesses and for other statutorily-specified reasons. For the small business exception, FDA has sought the assistance of the Small Business Administration to make the required size determinations. As of March 18, 1994, FDA has granted three one-year deferrals of payment of fiscal year 1993 application fees, seven one-year deferrals of payment of fiscal year 1994 application fees, and two 50 percent reductions of fiscal year 1993 application fees. FDA has denied two small business exception requests, and two small business exception requests are pending. Based on other statutory provisions, as of March 18, 1994, FDA has waived fiscal year 1993 fees for four applications, 16 products, and one establishment. FDA has waived

fiscal year 1994 fees for three applications, 26 products, and three establishments. FDA has denied requests to waive one fiscal year 1993 establishment fee and ten fiscal year 1993 and three fiscal year 1994 product fees. A limited number of waiver requests are pending.

In the near future, as announced in User Fee Correspondence 3, dated August 5, 1993, FDA plans to make public information about its actions granting or denying requests for waivers or exemptions, consistent with laws and regulations governing the disclosure of confidential commercial or financial information. For product and establishment fees the agency will disclose the names of entities requesting product or establishment fee waivers, the dates of the requests, the products or establishments for which the waivers were requested, the statutory provisions under which the fee waivers or reductions were sought, and FDA's resolution of the requests. FDA will not disclose information pertaining to application or supplement fee waivers requests until after the application or supplement is approved.

UNOBLIGATED BALANCE IN PDUF ACCOUNT

Mr. DURBIN. What is the unobligated balance in the Prescription Drug User Fee account as of the end of FY 93 and what do you expect it to be at the end of FY 94?

Mr. KESSLER. Of the \$36 million authorized and appropriated to FDA under the Prescription Drug User Fee Act in 1993, FDA had collected \$28.5 million and obligated \$8.9 million of that amount by the end of FY 93. This left us with net cash collected and carried forward of \$19.6 million. FDA also had accounts receivable or work in progress accounting for another \$9.1 million before waivers and exemptions were considered. This left us with unobligated budget authority at the end of FY 93 of about \$27 million, although we had available cash on hand against that authority of only about \$19.6 million at the close of the fiscal year.

The reason for the delayed receipt of some of these funds is two-fold. The first reason is that one-third of the revenues that come from application fees is submitted in two payments—half when the application is submitted, and the other half when FDA takes final action on the application. Thus, in any year, FDA will receive only about 65 percent of its application fee revenue authorized and appropriated to that year—the remaining 35 percent of the application fee for that year should be received by FDA within the next two fiscal years. The second reason is that in any fiscal year, some new products and establishments come on line that were not subject to fees in the previous year. In most cases, invoices for these additional products and establishments will not be billed until the end of the fiscal year, causing their receipts also to arrive in FDA in the following fiscal year.

WOMEN IN CLINICAL TRIALS

Mr. DURBIN. What is the FDA doing to ensure that drug protocol trials now include both men and women in the trials and that gender differences be reviewed?

Mr. KESSLER. On July 22, 1993, the Food and Drug Administration published the Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs. This guideline calls for better assessment of possible gender differences in response to new medications.

Specifically, this guideline encourages companies to include patients of both sexes in drug development trials, something which they have, in general, done in the past. In addition, they are to analyze the effectiveness and safety for significant differences in response between men and women, directing particular attention to possible pharmacokinetic effects associated with the phases of the menstrual period, menopause and use of oral contraceptives or estrogens. In this way, the guideline will help ensure that the safety and efficacy of drugs are adequately studied in the full range of patients who will receive therapy upon approval.

FDA reviewers have been asked to ensure that demographic analyses are performed pursuant to the guideline. Where such analyses are absent or inadequate, the FDA division may request that sponsors provide the appropriate analyses or, if warranted, may refuse to file the application. A letter was sent to the Pharma-

ceutical Manufacturers Association to convey this information to industry.

Mr. DURBIN. Do you note any reluctance on the part of drug companies to include women as part of their drug trials? Does this increase their liability?

Mr. KESSLER. The Agency has not noticed a reluctance on the part of drug companies to include women as part of their drug trials in phases 2 and 3 of the drug development process. As a matter of fact, in surveys conducted by FDA in 1983 and 1989, genders were represented to approximately the extent one would predict from the gender prevalence of the condition treated by the drug in the age group studied.

The new Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs reflects good drug development practice and gives flexibility to institutional review boards, investigators and patients in determining how best to ensure safety. However, the Agency has been asked to clarify the Guideline with respect to allowing sponsors, investigational review boards, and clinicians to balance liability risks attendant in fetal exposure against the importance of the data gained from the inclusion of women of childbearing potential in early trials.

Although FDA will work to resolve the issue of the balance of risks, it is impossible at this time to quantify the risk of tort liability from the inclusion of women in clinical studies. However, it has been demonstrated that there is more legal precedent for tort claims against sponsors that excluded women from clinical trials when there was subsequent harm to women who used the drug after approval.

GENERIC DRUG BACKLOG

Mr. DURBIN. What is the backlog of generic drug applications?

Mr. KESSLER. At the end of fiscal year 1993, there were 485 generic drug applications, both AADSs and ANDAs, pending. Of the 485 pending generic drug applications, 24 ANDAs were pending more than 180 days.

GENERIC DRUG APPROVALS

Mr. DURBIN. What is the average time for generic drug approvals in each of the past 10 years?

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

GENERIC DRUG APPROVALS

The median approval times for generic drug applications for the fiscal years since 1986 are shown below. We use the median rather than the average because it is less sensitive to extreme values, and gives a more accurate picture of approval times. Unfortunately we do not have this data for fiscal years 1984 and 1985.

Fiscal year:	Median approval time (Months)
1986	12.0
1987	12.0
1988	13.0
1989	17.0
1990	23.0

*Median
approval time*

1991	33.0
1992	34.5
1993	38.0

NOTE.—The approval time is determined from the date of receipt to the date of approval and takes into account the time the application is with the applicant/sponsor, which is approximately 18 percent of the total time to approval. Median approval time is high due to applications that were submitted during the 1980's and recently approved. These applications were caught up in the aftermath of the generic drug investigation. For example, the median approval time for ANDAs submitted after January 1990, is 26 months. Median review time is actually a better measure of FDA activity. Review time is defined as time from receipt until FDA's action. Approval time is a function of review time, number of review cycles, and time the application is with the applicant/sponsor. At the end of FY 1993, median review time for the first cycle was 4.4 months.

Mr. DURBIN. For the record, can you give us a table showing the resources allocated for the generic drug approval process for each of the past 10 years?

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

GENERIC DRUG EVALUATION

Fiscal year	FTE	Amount (thousands of dollars)
1984	116	5,597
1985	181	8,373
1986	227	11,733
1987	227	12,702
1988	213	12,344
1989	243	15,988
1990	300	20,574
1991	355	40,943
1992	452	41,670
1993	448	40,025

PESTICIDES

Mr. DURBIN. As you are well aware, Dr. Kessler, the issue of pesticide residues in foods has been a major issue with me for many years. Over the years, you have indicated that around 97–98 percent of the fruits, vegetables, and other food produced in the United States or imported either had no pesticide residues or levels detected were well within Federally permitted limits according to FDA standards and testing. Did you find this to continue to be true for fiscal year 1993?

Dr. KESSLER. Yes, our experience in 1993 indicates no change from previous years.

Mr. DURBIN. How many food microbiological samples did you take in each of the past 5 years?

Dr. KESSLER. Samples may be collected for a variety of problems, such as microbiological, filth, and additives. Based on additional information obtained during an investigation or by the laboratory, they may be analyzed for additional or even totally different attributes than what was indicated at the time of collection.

To provide the most accurate information, I will provide for the record, the number of samples analyzed for one or more microbiological attributes. For instance, a product analyzed for *Sal-*

monella sp. and *Listeria monocytogenes* is counted as one sample analyzed.

[The information follows:]

Microbiological sample analyses

1989	7,059
1990	7,593
1991	7,939
1992	8,778
1993	8,161

Mr. DURBIN. How many on domestic products?

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

Total domestic micro samples analyzed

1989	3,350
1990	3,270
1991	2,428
1992	2,097
1993	3,057

Mr. DURBIN. How many on imported products?

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

Total import micro samples analyzed

1989	3,709
1990	4,323
1991	5,511
1992	6,681
1993	5,104

Mr. DURBIN. How quickly can you turn your samples around so the product is not delayed in shipping?

Dr. KESSLER. FDA conducts microbiological analyses of foods, as well as drugs, cosmetics, and medical devices, under established sample analysis timeframes and center guidance through 20 or more compliance programs.

The Import and Domestic Food Safety Programs are representative microbiological programs. The Import Safety Program covers the analysis of imported foods for foodborne biological hazards. For FY 93, a total of 954 samples were collected under the Import Safety Program with 902 samples or 94.5 percent on time. Of these, 502 samples were compliance samples with 474 samples or 94.4 percent on time; and 452 samples were surveillance samples with 428 samples or 94.7 percent on time.

A variety of microbiological tests are performed on these samples, including tests for *Salmonella*, *E. Coli*, *C. Botulinum*, *Listeria* and *Staph Aureus*. The work day standard is 15 work days for import samples. This standard was met 95 percent for all microbiological samples analyzed.

Data on the number and timeliness of Class 3 or violative samples show that for FY 93, 10,944 violative samples were analyzed by FDA laboratories, 9,058 of these or 82.8 percent were completed on time.

In the analysis of domestic foods for foodborne biological hazards for FY 93, a total of 701 samples were analyzed with 662 samples or 94.4 percent on time.

FDA's field microbiology laboratories currently use biotechnology techniques—based upon immunology, molecular biology, genetics—and rapid method commercial test kits to assist in the screening of food products for microbial pathogens and their toxins. National training courses are held for the field scientists to ensure the proper use and interpretation of results from these methods.

Every effort is made to complete samples in a timely manner so as not to delay products which are in compliance. Research to develop additional rapid methods and testing strategies are underway in both field laboratories and CFSAN. NCTR is also working in collaboration with the field in developing rapid immunological based procedures for foodborne pathogens.

Mr. DURBIN. Do you do all the analysis at FDA laboratories or is it contracted out?

Dr. KESSLER. The data for the analyses provided includes only those performed in FDA field laboratories. While the Agency normally does perform all of its analyses in its own laboratories, contracts for analyses with other governmental agencies are sometimes negotiated. The most recent example is the FY 91-92 contract with USDA/AMS Gulfport, MS laboratory to analyze surveillance samples for certain pesticides.

SALMONELLA

Mr. DURBIN. How many outbreaks of *Salmonella* poisoning were reported to public health agencies throughout the country in 1993?

Dr. KESSLER. Information on the number of *Salmonella* outbreaks is not currently available. The Centers for Disease Control and Prevention will not have all of the State reports regarding *Salmonella* outbreaks that occurred until July or August of 1994.

FDA has been financially supporting the tabulation and computerization of this data by CDC for the past year. Data for the year 1992 are currently being entered. The last year that this information is available is 1991. In 1991, 113 outbreaks of salmonellosis were reported to CDC. A total number of 3,120 cases of human illness were involved in these outbreaks.

MINOR USE ANIMAL DRUGS

Mr. DURBIN. Drug companies are reluctant to develop veterinary drugs unless they have a projected market value that is near the \$10,000,000 per year category. We continue to receive reports of problems related to the lack of good veterinary drugs for many farm animals. How much did FDA expend on extramural and intramural work on minor use animal drug issues in FY 1993?

Dr. KESSLER. In FY 93, CVM expended \$438,843 on extramural work and \$20,237 on intramural work on minor use animal drug research.

Mr. DURBIN. What do you expect to allocate for this purpose in FY 94?

Dr. KESSLER. For FY 94, CVM's expected allocation for minor use animal drug research is \$317,648 for extramural work and \$15,000 for intramural work.

Mr. DURBIN. Is this done through contracts with universities and if so, which universities and how much to each?

Dr. KESSLER. CVM's extramural minor use animal drug research is done mostly through contracts with universities. I will be happy to provide the names of the universities and amounts they received for the record.

[The information follows:]

Minor use animal drug research contracts

Fiscal year 1993:

Ohio State University	\$265,585
Simon Fraser University	73,258

Fiscal year 1994 (estimated):

Ohio State University	224,648
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An interagency agreement with the U.S. Fish and Wildlife Service accounts for the remainder of CVM's extramural research funding, i.e., \$100,000 in FY 93 and \$93,000 anticipated in FY 94.

ANIMAL DRUG USER FEE STUDY

Mr. DURBIN. Dr. Kessler, the Prescription Drug User Fee Act directed that the Center of Veterinary Medicine conduct a feasibility study on the issue of user fees for animal drug applications. This study was supposed to be submitted to Congress by January 4 of this year. Can you tell when you expect to forward that to Congress?

Dr. KESSLER. We are working on that report, but it is not yet ready for submission to the Congress. The section of the Act you refer to required that we do a number of things before submission of the report. These included: assessing the current animal drug review process; determining if there were problems in the review process as regards timely review of animal drug product applications; developing goals and objectives to improve the review process; and determining the feasibility of charging fees to the animal drug industry to pay for the improvements needed. In addition, we were told to conduct this study in consultation with the animal drug industry.

We placed high priority on undertaking this study and I think we will all be pleased with the final product. There was considerable work to be done, as we wanted to assure a complete assessment of the animal drug review process and we made extensive efforts to seek and obtain input from the animal drug industry as we did the study. The collaboration with the industry has been gratifying in this process. In fact we had an excellent meeting with industry representatives less than two weeks ago on this subject.

Mr. DURBIN. How much did you spend to conduct this study?

Dr. KESSLER. The CVM User Fee Feasibility study was largely developed by the Center itself, costing \$110,000 and 1.2 FTEs.

ANIMAL DRUG APPLICATIONS

Mr. DURBIN. For the record, please provide us a table showing the number of animal health drug applications approved in each of the past 10 years by the Food and Drug Administration.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

Number of Animal Drug Applications Approved

Type of Application	FY 84	FY 85	FY 86	FY 87	FY 88	FY 89	FY 90	FY 91	FY 92	FY 93
Completed Original Investigational New Animal Drug Applications (INADAs)	262	185	110	222	196	210	298	307	413	366
Completed Supplemental INADAs	1,846	1,704	990	2,651	2,293	2,933	3,220	3,504	3,223	3,692
Completed Original and Abbreviated New Animal Drug Applications (NADAs)	192 *	163 *	302 *	247 *	152 *	40	20	51	53	48
Completed NADA Reactivations						124	103	87	97	92
Completed NADA Supplements	809	770	1,206	1,530	1,066	1,027	1,159	997	1,003	545
Completed NADA Amendments	N.A.	N.A.	N.A.	N.A.	N.A.	275	279	250	364	242

* Includes Reactivations.

N.A. this information was not kept as a separate statistic until FY 89.

SAFE MEDICAL DEVICES ACT OF 1990

Mr. DURBIN. Describe for us your activity related to compliance with the Safe Medical Device Act of 1990?

Dr. KESSLER. I will supply a detailed description for the record. [The information follows:]

SAFE MEDICAL DEVICES ACT OF 1990

FDA has made substantial progress in carrying out its new regulatory authorities provided by the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992. To implement some provisions and to clarify procedures for provisions already in effect, FDA published numerous documents in the *Federal Register*. As of February 1994, FDA had published a total of six notices, six proposed rules, three final rules, one tentative final rule, and one interim final rule. FDA is currently working on one notice, two proposed rules, and six final rules.

In addition to the rule-making efforts, FDA has performed other activities to implement the various SMDA provisions. These include:

A conference to educate health professionals on user facility reporting and to solicit their input regarding FDA's implementation strategy.

A public hearing on implementation of the combination products provision.

Use of new enforcement authorities to: suspend a PMA; require manufacturers of certain devices to conduct postmarket surveillance studies; require manufacturers to cease distribution of devices that may cause serious, adverse health consequences; assess civil monetary penalties; require device user facilities and distributors to report certain adverse experience data; and require manufacturers of certain medical devices to develop patient tracking systems.

Creation of the mandated Office of International Relations and External Affairs.

FDA is continuing to implement the provisions and to comply with the requirements of the Act. FDA is: summarizing the results of the SMDA-mandated evaluation of the compliance and cost benefit of the medical device user facility reporting requirements; developing the "special controls" strategy for class II devices; and developing a strategy for addressing class III pre-Amendments devices. FDA will continue to use its expanded enforcement authorities where necessary to ensure that the public health is not compromised and that serious violations of the Food, Drug, and Cosmetic Act are dealt with promptly and appropriately.

MANAGEMENT INFORMATION SYSTEM

Mr. DURBIN. Last year, Dr. Kessler, you testified that you were going to move ahead to build a management information system that will enhance and speed up the product approval process. A good piece of this information system was the computer information network. You referred to the program as the SMART system. Could you describe for us how much you have spent during fiscal years 1993 and 1994 on this process and what the total plans are for a computerized system?

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

SUBMISSION MANAGEMENT AND REVIEW TRACKING PROGRAM (SMART)

The Submission Management and Review Tracking program (SMART) is designed to reduce the time required to bring new products to market through process improvements and the use of information systems technologies in the preparation, submission, review, and tracking of product applications.

Building on the experience gained from the CANDA program within CDER, SMART will enhance communications at all levels and will facilitate electronic information interchange between the FDA and industry during the entire product life cycle. SMART will provide Agency reviewers with a consistent access mechanism to a diversity of information from both current and past submissions as well as a range of software tools and expert systems to facilitate information analysis and review document preparation. A key element of this effort will be the development of standardized nomenclatures and data architecture for the scientific information contained

in industry submissions. These standards will facilitate both information exchange and analysis.

SMART will also have a major impact on the Agency's ability to track product applications throughout the review cycle. Integration with Agency project management initiatives will ensure proper notification, improved reviewer workload management, and smooth routing of the application through the process. The SMART program will be approached in a phased manner to provide short term benefits to the reviewer community while working toward the ultimate goal of an Agency approach to management of product applications.

The primary emphasis during FY 93 and FY 94 has been on developing the vision and building the infrastructure necessary to support this program. Funded principally by user fees, the SMART program will rely heavily on contract resources to accomplish most of the information system objectives. The first of these contract (to support development of standardized nomenclatures) was competitively awarded during the second quarter of FY 93.

The second contract, designed to provide systems development support, is targeted for award in the third quarter, FY 94. The SMART program team, headed by a Medical Reviewer, will work with the user community to define support requirements and provide technical direction to the contractor. Resources are summarized below:

Fiscal year:	<i>Funds (thousands of dollars)</i>
1993	88
1994	4,405
1995 ¹	6,733
1996 ¹	8,549
1997 ¹	8,811
1998 ¹	7,323
1999 ¹	7,435

¹ Estimate.

ADVISORY COMMITTEES

Mr. DURBIN. How many of the Institute of Medicine's recommendations on advisory committees have you initiated?

Dr. KESSLER. FDA has initiated 33 of the 36 recommendations on advisory committees made by the Institute of Medicine.

Mr. DURBIN. For the record, please provide us a list of all advisory committees used during fiscal years 1992 and 1993 and the cost associated with each advisory committee and your proposals for fiscal years 1994 and 1995.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

FDA PUBLIC ADVISORY COMMITTEE COSTS

COMMITTEE NAME	FY '92 Act.	FY '93 Act.	FY '94 Proj.	FY '95 Proj.
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee)	\$ 26,272	\$ 48,110	\$ 67,026	\$ 89,368
Allergenic Products Advisory Committee	44,912	64,809	103,233	137,644
Anesthetic & Life Support Drugs Advisory Committee	77,675	87,264	125,165	166,887
Anti-Infective Drugs Advisory Committee	71,776	126,221	203,791	271,722
Antiviral Drugs Advisory Committee	89,009	104,293	139,086	185,448
Arthritis Advisory Committee	79,742	65,420	90,403	120,538
Biological Response Modifiers Advisory Committee	94,226	71,187	158,894	211,859
Blood Products Advisory Committee	225,347	245,045	267,092	356,123
Board of Tea Experts	8,568	8,999	N/A	N/A
Cardiovascular and Renal Drugs Advisory Committee	76,433	143,415	158,787	211,716
Dermatologic Drugs Advisory Committee	57,134	63,056	139,437	185,916
Device Good Manufacturing Practice Advisory Committee	0	0	0	0
Drug Abuse Advisory Committee	84,678	96,522	206,665	275,554
Endocrinologic and Metabolic Drugs Advisory Committee	95,425	40,693	147,725	196,967
Fertility and Maternal Health Drugs Advisory Committee	67,321	53,433	111,410	148,547
Food Advisory Committee	N/A	244,031	216,266	288,355
Gastrointestinal Drugs Advisory Committee	67,103	93,333	113,492	151,323
Generic Drugs Advisory Committee	52,239	113,977	194,649	259,532
Medical Devices Advisory Committee (16 devices panel)	649,844	595,843	1,153,341	1,537,788
Medical Imaging Drugs Advisory Committee	55,460	55,986	96,711	128,948
National Mammography Quality Assurance Advisory Committee	N/A	N/A	563,939	751,919

NCTR'S RESEARCH EFFORTS

Mr. DURBIN. If your budget is approved, what will that do to the research efforts of the NCTR?

Dr. KESSLER. The FY 95 budget "straight-lines" FY 94 dollars and decreases FTEs by 14 for NCTR. To implement this budget, we will reprioritize and perhaps delay new research initiatives. A thorough review of the NCTR program has resulted in an intensive reconsideration of program priorities to determine what programs should be reduced, delayed, or eliminated in the light of important, new research needs for example, the effects of estrogenic compounds found in plants and other foods; the potent corn contaminant, fumonisin; the pediatric drug, chloral hydrate; low-level electromagnetic radiation; understanding and defining secondary mechanisms of carcinogenicity and whether such effects may differ from direct effects covered by the Delaney Clause; and the safety of products developed through transplanted genes.

Significant redirection during the last two years within NCTR was made to fund these newly identified, high-priority FDA projects. Since only the high-priority and long-term projects were left intact in the earlier effort, the proposed savings will delay some of the newly identified efforts I mentioned while others may be terminated.

Mr. DURBIN. For the record, please provide a five-year table, starting with FY 1991, showing the resources used by NCTR.

Dr. KESSLER. I will be happy to provide the information for the record.

[The information follows:]

Funding for NCTR

[Dollars in thousands]

Fiscal year:	Amount
1991	\$31,407
1992	31,097
1993	32,986
1994 estimate	33,756
1995 estimate	33,756

SEAFOOD SAFETY

Mr. DURBIN. Recently Dr. Kessler, you announced a new seafood inspection plan. Many critics of food safety inspection programs say this is only the first step and much more has to be done. Do you have additional plans to increase seafood safety efforts?

Dr. KESSLER. There will always be more to be done. Scientific knowledge can and should always be advanced, technologies improved, regulatory strategies refined and enhanced. Partly for that reason, we would not characterize FDA's recent seafood initiative—the issuance of proposed regulations that would require processors and importers to establish a system of preventive controls known as Hazard Analysis Critical Control Point, or "HACCP"—as a first step. Rather, we regard it as the next logical step in a program that spans decades.

Many other activities are ongoing. FDA is pursuing a major enhancement of its program relating to seafood imports through the development of international agreements with U.S. trading partners. Imported seafood constitutes the majority of seafood

consumed in this country. The purpose of an agreement will be mutual recognition of the equivalency of each country's regulatory program for seafood based on HACCP principles.

When an agreement is in place, inspections by foreign regulatory authorities of overseas processors that ship to the U.S. will be equivalent to U.S. inspections and regularly verified by FDA. They will provide additional assurance of safety to U.S. consumers and will enable FDA to better focus its resources on problem areas. Several countries that export seafood to the U.S. have shown great interest in entering into such agreements and negotiations have already begun.

FDA is also meeting with State officials to explore inspection partnership arrangements based, again, on the FDA seafood HACCP regulations. The U.S. seafood program has been criticized in the past as being a patchwork of Federal and State efforts that have never been effectively integrated. This criticism is not entirely valid. However, there is no question that a Federal-State partnership based on mandatory HACCP requirements and HACCP-based inspections can maximize the impact of the resources available to FDA and the states for the regulation of seafood. Such a partnership would be a significant development.

FDA continues to pursue numerous research projects. Many are designed to enhance the state of knowledge regarding hazard analysis and control. The results of this research will strengthen the ability of FDA and the industry to implement and verify HACCP systems as required by the proposed regulations. There is ongoing research to develop better indicators of water quality and to detect pathogens. Other projects are designed to learn more about *Vibrio vulnificus*, the marine bacterium responsible for several deaths annually in the U.S. among certain medically compromised individuals who consume raw molluscan shellfish.

FDA is conducting research into marine toxins, and it is hoped that this research will facilitate the development of a rapid detection method for ciguatoxin in tropical and subtropical reef fish. Illnesses from this toxin are one of the three most reported types of illness from seafood. We are also working on ways to better detect the presence of scombrototoxin in those species of fish that can become toxic if they are time/temperature abused after catch. Scombrototoxin is also one of the three most reported kinds of seafood-related illness. These projects are only a few examples of current FDA research.

Mr. DURBIN. For the record, please provide a five-year table, starting with FY 1991, showing the manpower and funding resources used for seafood safety.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

SEAFOOD SAFETY RESOURCES FY 1991-FY 1995

[Dollar amounts in thousands.]

	Fiscal year	FTEs	Amount
1991 actual	492	\$40,300
1992 actual	522	43,326
1993 actual	507	43,600

SEAFOOD SAFETY RESOURCES FY 1991-FY 1995—Continued

(Dollar amounts in thousands.)

	Fiscal year	FTEs	Amount
1994 actual		497	44,000
1995 estimate		497	44,000

NATIONAL SHELLFISH SANITATION PROGRAM

Mr. DURBIN. As you did last year, Dr. Kessler, could you provide us with a synopsis of the activities related to the National Shellfish Sanitation Program?

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

FY 1993 ACCOMPLISHMENTS FDA SHELLFISH SANITATION PROGRAM—OCTOBER 1, 1992–SEPTEMBER 30, 1993

EVALUATIONS, TRAINING, TECHNICAL ASSISTANCE

Nineteen state shellfish sanitation programs were evaluated for compliance with NSSP Manual criteria.

Four international shellfish sanitation programs were evaluated for compliance with NSSP Manual criteria, and with the MOU with FDA for exporting fresh and fresh frozen molluscan shellfish to the U.S.

Three state and 10 international laboratories supporting shellfish sanitation programs were evaluated for compliance with NSSP laboratory criteria. The international lab evaluations were conducted in New Zealand and Chile.

Four individuals were certified as state or international program Laboratory Evaluation Officers (LEO).

Three Plant Standardization training courses were conducted. Two were presented to state and international standardization officer candidates, and the third to Army food inspection staff.

Thirty-one state and FDA candidates were standardization in plant inspections.

Uniformity in evaluations is a long term FDA commitment to improve compliance within the National shellfish Sanitation Program (NSSP).

THE INTERSTATE SHELLFISH SANITATION CONFERENCE (ISSC)

The ISSC now has a full-time ISSC Executive Director's Office which was established through an FDA/NOAA grant. This will provide for more effective and timely cooperation among federal and state regulatory agencies and industry to protect the public health.

SEAFOOD ILLNESSES

Mr. DURBIN. Could you tell us what the incidence of reported seafood illnesses was for fiscal year 1993, whether that was from fish or shellfish?

Dr. KESSLER. During fiscal year 1993, FDA received 211 consumer complaints about injury and/or illness symptoms, treatment by a physician, or a hospital visit associated with the Consumption of fishery or seafood products. Of these consumer complaints, 161 concerned fin fish products, 25 concerned shellfish products, 17 concerned crustacean products, and eight concerned other unspecified fishery products.

APPROVED AIDS THERAPIES

Mr. DURBIN. As we watch the spread of AIDS across the country and it invades the heterosexual population, the need to find preventive vaccines and cures grows. As you did last year, Dr. Kessler,

please provide us a table that shows the therapies and drugs that have been approved for AIDS and the time it took to approve those drugs.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

**DRUGS CURRENTLY APPROVED BY THE FDA
FOR AIDS AND AIDS-ASSOCIATED CONDITIONS**

<u>DRUG</u>	<u>STAMP DATE</u>	<u>APPROVAL DATE</u>	<u>APPROVAL TIME</u>
<u>Antiretroviral Drugs</u>			
Retrovir Capsules (Ziduvodine, AZT)	02 DEC 86	19 MAR 87 (NDA)	3.5 months
Retrovir Syrup	28 OCT 88	28 SEP 89 (NDA)	11 months
Retrovir Injection	01 FEB 89	02 FEB 90 (NDA)	12 months
Videx (Didanosine, ddI) (for advanced HIV infection when there is intolerance to or no response to Zidovudine)	06 APR 91	09 OCT 91 (NDA)	6 months
<u>Drugs for AIDS-Associated Conditions</u>			
Interferon A Injection (Intron A)	30 SEP 83	21 NOV 88 (PLA)	5 years + 2 months
(Roferon A) (for Kaposi's Sarcoma)	24 OCT 84	21 NOV 88 (PLA)	4 years
Cytovene (Ganciclovir) (For CMV Retinitis)	29 Dec 86*	23 JUN 89*(NDA)	
*NDA withdrawn 23 NOV 88 and resubmitted 1 MAY 89			
Diflucan Tablets (Fluconazole) (for Cryptococcal meningitis, candidiasis)	02 MAR 89	29 JAN 90 (NDA)	11 months
Diflucan Injection	21 MAR 89	29 JAN 90 (NDA)	11 months
Nebupent (Aerosolized Pentamidine) (for prevention of PCP)	29 JUL 88	15 JUN 89 (NDA)	11 months
Epogen (Erythropoietin) (for ZDV-related anemia)	12 SEP 90	31 DEC 90 (NDA)	1 5 . 5 months

FDA Approved
Drugs Continued

<u>DRUG</u>	<u>STAMP DATE</u>	<u>APPROVAL DATE</u>	<u>APPROVAL TIME</u>
Foscavir (Foscarnet) (for CMV retinitis)	04 MAY 90	27 SEP 91 (NDA)	17 months
FDA Approved Drugs Continued			
Sporanox (itraconazole) (for histoplasmosis and blastomycosis)	31 MAY 90	11 SEP 92 (NDA)	2 years + 4.5 months
Mepron (atovaquone) (for mild to moderate PCP in patients intolerant of TMP-SMX)	24 APR 92	25 NOV 92 (NDA)	7 months
Mycobutin (rifabutin for MAC)	08 OCT 91	23 DEC 92 (NDA)	14 months
Marinol* (Dronabinol) (for anorexia and weight loss associated with AIDS)	19 AUG 92	22 DEC 92 (SUP)	5 months
Megace * (megestrol acetate) (for anorexia, cachexia, or an unexplained weight loss in patients with AIDS)	1 APR 92	10 SEP 93 (NDA)	1 year 5 months
NeuTrexin (trimetrexate glucuronate administered concurrently with leucovorin)	1 FEB 93	17 DEC 93 (NDA)	10.5 months

FDA Approved
Drugs Continued

<u>DRUG</u>	<u>STAMP DATE</u>	<u>APPROVAL DATE</u>	<u>APPROVAL TIME</u>
(for moderate to severe Pneumocystis carinii pneumonia [PCP])			
FDA Approved Drugs Continued			
Clarithromycin * (for the treatment of disseminated mycobacterial infections due to <u>Mycobacterium avium</u> and <u>Mycobacterium Intracellulare</u> [<u>Mycobacterium avium</u> complex-MAC])	30 OCT 92	23 DEC 93 (NDA)	1 year 2 months
Immune Globulin Intravenous* (Human) (IGIV) (for use in HIV-infected children to decrease the frequency of bacterial infections, increase the time from serious bacterial infections, and decrease the frequency of hospitalizations)	14 AUG 90	03 JAN 94 (PLA)	3 years 5 months
Bactrim Trimethoprim/ Sulfamethoxazole* (for the prophylaxis against <u>Pneumocystis carinii</u> pneumonia in individuals who are immunosuppressed and considered to be at an increased risk of developing <u>Pneumocystis</u> <u>carinii</u> pneumonia)	24 AUG 92	07 JAN 94 (NDA)	1 year 4 months

FDA Approved
Drugs Continued

<u>DRUG</u>	<u>STAMP DATE</u>	<u>APPROVAL DATE</u>	<u>APPROVAL TIME</u>
Septra Trimethoprim/ Sulfamethoxazole* (for the prophylaxis against <u>Pneumocystis carinii</u> pneumonia in individuals who are immunosuppressed and considered to be at an increased risk of developing <u>Pneumocystis</u> <u>carinii</u> pneumonia)	18 JUN 92	07 JAN 94 (NDA)	1 year 6 months

* New Indication

Prepared by:
Office of AIDS and Special Health Issues
March 21, 1994

INDS AND AIDS

Mr. DURBIN. Usually the drugs for AIDS applications are provided the designation of 1-AA. How many investigational new drug applications do you currently have with this designation, and how many of them are for AIDS-related conditions?

Dr. KESSLER. All drugs for AIDS or AIDS-related diseases are classified as AA but not all of the products for AIDS are new molecular entities—chemical type 1. Of the 18 new drug applications—NDAs—classified as AA, nine are 1-AA and nine are non-1. Information available on INDs is incomplete. Of the active commercial INDs for which data is available, 38 INDs are classified as AA; 33 of these INDs are 1-AA and five are not.

There is a misperception about the classification “1-AA.” Many people have referred to all AIDS drugs being classified as 1-AA. This is incorrect. All AIDS drug applications are classified as “AA”, but not all are classified as “1.”

The IND/NDA classification system in the Center for Drug Evaluation and Research is a way of describing drug applications upon initial receipt and throughout the review process, and prioritizing their review. Each application has at least two classifications—chemical and therapeutic.

The chemical classification, Types 1–7, is a fixed objective rating that describes FDA’s assessment of the drug’s relationship to active moieties already marketed or approved in the U.S.

The therapeutic classification, priority or standard, is a subjective rating describing FDA’s estimate during the drug’s IND development, of its potential therapeutic value, and the finally, its assessment, based on information available at the time of NDA approval, of the drug product’s therapeutic value.

The therapeutic potential and usually the chemical type are mutually exclusive classifications. Other classifications such as, type AA—AIDS drug classification, are not mutually exclusive.

AIDS FUNDING

Mr. DURBIN. For the record, would you please provide us a five-year historical table that shows the funding provided for AIDS activities broken out by drugs, biologics devices, or other categories.

Dr. KESSLER. I will be happy to provide that information for the record.

[The information follows:]

FUNDING FOR AIDS ACTIVITIES

[Dollars in thousands]

	1991	1992	1993	1994	1995
Human drugs	\$20,921	\$24,583	\$25,275	\$25,235	25,235
Biologics	33,599	39,043	37,549	37,408	37,408
Medical devices	8,875	8,676	9,804	9,756	9,756
Total FDA	63,395	72,302	72,628	72,399	72,399

Mr. DURBIN. Please provide an object class table for the resources available for AIDS for fiscal years 1993, 1994, and 1995.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

FDA RESOURCES FOR AIDS 1993-1995

[Dollars in thousands]

	1993	1994	1995
Personnel comp and benefits	\$37,630	\$39,172	\$39,798
Travel and transportation	515	525	525
Rent, commun. and utilities	420	425	425
Printing	400	405	405
Contracts and other services	19,038	19,050	19,050
Supplies and materials	5,545	5,500	5,500
Equipment	9,100	7,322	6,696
Total FDA	72,648	72,399	72,399

AIDS BUILDING

Mr. DURBIN. In 1989, Congress provided \$25 million to construct a building on the NIH campus for the benefit of its AIDS work. Last year, you testified that the design of Phase Two was approximately 70 percent complete and that you hoped to go to construction in March 1993. Your FY 95 budget proposes to use about \$5,000,000 for the opening of the new AIDS building located on the NIH campus. How will these funds be used?

Dr. KESSLER. The \$5,000,000 you refer to is not for the opening of the new AIDS building. Rather, it is our best estimate of the amount that must be transferred from FDA to NIH to provide annual on-site management services to the new building.

OBJECT CLASS

Mr. DURBIN. For the record, please provide us an object class table for all FDA resources for fiscal years 1993, 1994, and 1995.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

OBLIGATIONS BY OBJECT CLASS

[In thousands of dollars]

	1993 actual	1994 estimate	1995 estimate
11. Full-time permanent	\$375,909	\$409,521	\$437,137
11. Other than full-time perm	24,523	27,302	29,142
11. Other personnel comp	14,689	16,059	17,149
11. Special personal svcs pay	292	322	336
11. Total personnel comp	415,413	453,204	483,764
12. Civilian prsnl benefits	87,252	92,826	99,084
13.0 Benefits former personnel			
Total pay and benefits	502,665	546,030	582,848
21.0 Travel and transp of person	19,278	22,832	21,479
22.0 Transportation of things	1,336	2,340	2,694
23.1 Rent payments to GSA	26,066	48,575	48,575
23.2 Rent payments to others	5,409	8,208	10,626
23.3 Communications, utilities and miscellaneous charges	22,104	25,882	28,166
24.0 Printing and reproduction	3,507	4,460	4,865
25. Consulting Services	4,783	5,149	5,355
25.2 Other services	41,941	60,929	71,190
25. Purchases of Goods and Services from Government Accounts	36,603	39,376	38,145
25. Operation of GOCOs	15,228	23,612	22,854

OBLIGATIONS BY OBJECT CLASS—Continued

[In thousands of dollars]

	1993 actual	1994 estimate	1995 estimate
25. Research and Development Contract	31,111	33,460	35,915
26.0 Supplies and materials	25,836	31,490	34,896
31.0 Equipment	33,947	56,281	53,248
32.0 Land and structure	14,327		3,146
41.0 Grants, subsidies and Contributions	16,834	17,000	17,550
42.0 Ins claims and indemnities	2,227	1,374	1,380
99.0 Subtotal	803,202	926,548	982,932
PDUFA	(8,949)	(56,284)	(79,423)
Deficit user fees			(228,000)
Device user fees			(24,000)
MQSA collections			(6,500)
Subtotal direct	794,253	870,264	645,009
Contingency Fund			
CRADAS	221	117	324
Total direct	794,474	870,381	645,333
99.0 Reimbursable obligation	14,895	70,064	351,703
Carry over:			
Contingency		3,682	
CRADAS		198	
Buildings and facilities		18,285	
99.9 Total obligations	809,369	962,610	997,036

Mr. DURBIN. For the record, please update the tables showing the distribution of resources that appear on pages 66 and 67 of last year's hearing record.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

DISTRIBUTION OF RESOURCES

	FY 1993 Actual		FY 1994 Current Estimate		FY 1995 Estimate	
	\$000	FTE	\$000	FTE	\$000	FTE
Foods						
Chemical Safety of Foods.....	73,273	949	79,344	949	79,344	898
Microbiological Safety of Foods.....	94,295	1,306	102,107	1,306	102,107	1,235
Nutrient Quality and						
Food Labeling.....	32,518	381	35,212	381	35,212	361
Cosmetic Safety and Labeling.....	4,604	59	4,985	59	4,985	56
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TOTAL, FOODS.....	204,690	2,695	221,648	2,695	221,648	2,550
Human Drugs						
New Drug Evaluation/Orphan Drugs....	75,089	852	90,052	916	99,992	1,049
Orphan Drug Evaluation.....	11,455	16	15,150	16	15,150	15
Generic Drug Evaluation.....	40,025	448	46,724	448	46,724	423
OTC Drug Evaluation.....	7,954	90	7,994	90	7,994	85
Drug Quality Assurance.....	48,591	692	48,840	692	48,840	652
Bioresearch Monitoring.....	12,311	170	16,644	177	18,715	204
Health Fraud.....	4,594	61	4,618	61	4,618	58
Postmarketing Surveillance						
& Epidemiology.....	7,386	76	7,424	76	7,424	72
Prescription Drug Advertising						
and Labeling.....	4,242	44	4,264	44	4,264	42
	-----	-----	-----	-----	-----	-----
TOTAL, HUMAN DRUGS.....	211,647	2,449	241,710	2,520	253,721	2,600
Biologics						
Blood & Blood Products.....	51,204	533	52,300	549	55,252	567
Therapeutic Products.....	30,273	279	49,674	312	54,463	374
Vaccines & Allergenic Products.....	16,804	157	29,360	179	32,746	223
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TOTAL, BIOLOGICS.....	98,281	969	131,334	1,040	142,462	1,164

	FY 1993 Actual		FY 1994 Current Estimate		FY 1995 Estimate	
	\$000	FTE	\$000	FTE	\$000	FTE
Animal Drugs and Feeds						
Pre-Approval Evaluation.....	18,319	231	20,061	231	20,061	219
Monitoring of Marketed Drugs and Feeds.....						
	19,698	254	21,572	254	21,572	240
	-----	-----	-----	-----	-----	-----
TOTAL, ADF.....	38,017	485	41,633	485	41,633	459
Devices & Radiological Products						
Surveillance and Enforcement.....	64,165	883	74,975	929	82,291	979
Product Evaluation.....	36,494	459	44,277	509	66,718	795
Education & Assistance.....	15,234	185	19,048	186	19,433	181
Risk Assessment.....	13,132	156	15,014	157	15,372	151
	-----	-----	-----	-----	-----	-----
TOTAL, DEVICES.....	129,025	1,683	153,314	1,781	183,814	2,106
National Center for Toxicological Research						
Integrated Research.....	18,251	141	18,677	141	18,677	133
Methods Development.....	14,735	116	15,079	116	15,079	110
	-----	-----	-----	-----	-----	-----
TOTAL, NCTR.....	32,986	257	33,756	257	33,756	243
PROGRAM MANAGEMENT.....	45,442	401	49,012	398	48,973	377
GSA RENT.....	26,066	--	48,575	--	48,575	--
BUILDINGS AND FACILITIES.....	19,664	--	8,350	--	8,350	--
	=====	=====	=====	=====	=====	=====
TOTAL.....	805,818	8,939	929,332	9,176	982,932	9,499
		<u>1/</u>		<u>2/</u>		<u>3/</u> <u>4/</u>

1/ Reflects comparable transfer of \$2,616,000 and 39 FTE in FY 1993, and \$2,784,000 and 36 FTE in FY 1994 from Office of the Secretary/Office of General Counsel, to FDA's Program Management line. 34 FTE and \$2,745,000 are officially transferred from OS/OGC to FDA in FY 1995.

2/ Includes \$56,284,000 for PDUFA (\$54,000,000 appropriated and a supplemental request of \$2,284,000 to cover inflation). Also includes \$30,000,000 in Devices: \$20,000,000 for Safe Medical Devices Act and \$10,000,000 for Mammography Quality.

3/ Includes \$79,423,000 for PDUFA; \$24,000,000 for Device User Fees; \$6,500,000 for MQSA collections; and deficit user fees of \$228,000,000.

4/ Reflects a reduction of 384 FTE.

DRUG APPLICATION

Mr. DURBIN. For the record, would you please update the table that appears on page 69 of last year's hearing which shows the summary of drug applications and the workload for each?

Dr. KESSLER. I would be pleased to submit that information for the record.

[The information follows:]

DRUG APPLICATION SUMMARY

	Fiscal year				
	1990	1991	1992	1993	1994
INDs:					
Number received	1,473	1,963	2,452	2,413	2,500
Reviews/action	2,378	3,609	3,707	4,015	4,300
Number active-end of year	9,506	9,958	10,261	10,682	11,000
NDA:					
Applications received	106	108	89	97	100
Total actions	241	275	286	236	250
Number awaiting action over 180 days—end of year ..	90	65	35	38	25
Total number approved	69	62	86	83	85
Time from receipt to approval (mean)	(31.7)	(29.2)	(30.0)	(26.9)	(20–25)
NDA supplements:					
Originals and amendments received	3,625	3,030	2,954	3,257	3,500
Total actions	2,085	2,221	2,291	2,157	2,300
Number awaiting action—end of year	2,476	2,716	2,627	2,598	2,600
Supplements approved	1,279	1,570	1,415	1,308	1,400
ANDAs:					
Original ANDA/AADA received	352	300	339	308	340
Resubs, amendments, supplements, reports, corresp. ¹	15,600	12,500	6,120	5,928	5,950
Total number ANDA/AADA appr.	73	145	239	215	240
Median review time from receipt to approval (months includes time application is with applicant. ²	23	33	34.5	38	35

¹ As of FY 1989, "resubmission" had the same meaning as "amendment" for purposes of this table. Figures shown do not reflect numbers for correspondence which are no longer tabulated.

² The approval time is determined from the date of receipt to the date of approval and takes into account the time the application is with the applicant/sponsor, which is approximately 18 percent of the total time to approval. Median approval time is high due to applications that were submitted during the 1980's and recently approved. These applications were caught up in the aftermath of the generic drug investigation. For example, the median approval time for ANDAs submitted after January 1990, is 26 months. Median review time is actually a better measure of FDA activity. Review time is defined as time from receipt until FDA's action. Approval time is a function of review time, number of review cycles, and time the application is with the applicant/sponsor. As of January 1993, median review time for the first cycle was 4.4 months.

Mr. DURBIN. Please provide a ten-year table showing the average time for a NDA approval process and for new molecular entities.

Dr. KESSLER. I would be happy to provide this information for the record.

[The information follows:]

NDA MEAN AND MEDIAN APPROVAL TIMES

[In months]

Calendar year	Mean	Median	Total approvals	Total "SC" approvals	Total "non-SC" approvals
1982	22.4	17.5	116	59	57
1983	20.9	14.7	94	53	41
1984	24.2	18.7	142	75	67
1985	24.9	22.1	100	35	65
1986	27.9	21.6	98	37	61
1987	29.0	27.0	68	16	52
1988	28.9	21.8	67	25	42
1989	30.9	25.9	87	19	68
1990	30.0	25.2	64	2	62
1991	28.5	23.4	63	10	53

NDA MEAN AND MEDIAN APPROVAL TIMES—Continued

(In months)

Calendar year	Mean	Median	Total approvals	Total "5C" approvals	Total "non-5C" approvals
1992	26.3	20.0	91	21	70
1993	33.1	24.1	70	18	52

Note.—Beginning in 1992, FDA began using new designations. "5C" (already marketed, "me-too") is now 5S ("S" means standard review, substantially equivalent). The other designation is "P" for priority review, therapeutic gain. P, S have replaced A, B, C.

NEW MOLECULAR ENTITIES ("1s") MEAN AND MEDIAN APPROVAL TIMES

(In months)

Calendar year	Mean	Median	Number of approvals
1982	28.8	21.2	28
1983	28.5	26.9	14
1984	39.1	31.1	22
1985	31.9	29.8	30
1986	34.1	32.9	20
1987	32.3	29.9	21
1988	31.3	27.2	20
1989	32.5	29.3	23
1990	27.7	24.3	23
1991	30.3	22.1	30
1992	28.5	22.6	26
1993	26.5	23.0	25

Mr. DURBIN. Also provide a table for the average review time for ANDA's since fiscal year 1986.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

Average review time for ANDA's

Fiscal year:	Median review times (Months)
1986	12
1987	12
1988	13
1989	17
1990	23
1991	33
1992	34½
1993	38

NOTE.—Review time is defined as time from receipt until FDA's approval. Approval time is a function of review time, number of review cycles, and time the application is with the applicant/sponsor.

EXPENDITURES FOR ORPHAN DRUGS

Mr. DURBIN. Please provide for the record an object class table of your expenditures in the orphan drug product area for fiscal years 1993, 1994, and 1995.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

ORPHAN PRODUCT EXPENDITURES FOR 1993-95

(Dollars in thousands)

	1993	1994	1995
Personnel compensation and benefits	\$903	\$948	\$919
Travel and transportation	40	50	50
Other services	1,167	1,852	1,881
Supplies and materials	200	300	300
Grants	9,145	12,000	12,000
Total FDA	11,455	15,150	15,150

ORPHAN DRUG APPROVALS

Mr. DURBIN. Please provide a list of all products approved as part of the Orphan Drug Product Authorities.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

APPROVED ORPHAN PRODUCTS
January 1983 to March 24, 1994

NAME Generic Name TN = Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD = Date Designated MA = Marketing Approval
ALDESLEUKIN TN= PROLEUKIN	TREATMENT OF METASTATIC RENAL CELL CARCINOMA.	CHIRON CORPORATION 4560 HORTON STREET EMERYVILLE CA 94608-2916 DD 09/14/88 MA 05/05/92
ALGLUCERASE INJECTION TN= CEREDASE	REPLACEMENT THERAPY IN PATIENTS WITH GAUCHER'S DISEASE TYPE I.	GENZYME CORPORATION ONE KENDALL SQUARE CAMBRIDGE MA 02139 DD 03/11/85 MA 04/05/91
ALPHA-1-PROTEINASE INHIBITOR TN= PROLASTIN	REPLACEMENT THERAPY IN THE ALPHA-1-PROTEINASE INHIBITOR CONGENITAL DEFICIENCY STATE.	CUTTER BIOLOGICAL P.O. BOX 1986 BERKELEY CA 94701 DD 12/07/84 MA 12/02/87
ALTRETAMINE TN= HEXALEN	TREATMENT OF ADVANCED ADENOCARCINOMA OF THE OVARY.	U.S. BIOSCIENCE, INC. 100 FRONT STREET WEST CONSHOHOCKEN PA 19428 DD 02/09/84 MA 12/26/90
ANTIHEMOPHILIC FACTOR (RECOMBINANT) TN= KOGENATE	PROPHYLAXIS AND TREATMENT OF BLEEDING IN INDIVIDUALS WITH HEMOPHILIA A OR FOR PROPHYLAXIS WHEN SURGERY IS REQUIRED IN INDIVIDUALS WITH HEMOPHILIA A.	MILES, INC. 4TH & PARKER STREETS BERKELEY CA 94701 DD 09/25/89 MA 02/25/93
ANTITHROMBIN III (HUMAN) TN= THROMBATE III (SHARING EXCLUSIVITY)	REPLACEMENT THERAPY IN CONGENITAL DEFICIENCY OF AT-III FOR PREVENTION AND TREATMENT OF THROMBOSIS AND PULMONARY EMBOLI.	MILES, INC. P.O. BOX 1986 BERKELEY CA 94701 DD 11/26/84 MA 12/30/91
ANTITHROMBIN III HUMAN TN= Atnativ	FOR THE TREATMENT OF PATIENTS WITH HEREDITARY ANTITHROMBIN III DEFICIENCY IN CONNECTION WITH SURGICAL OR OBSTETRICAL PROCEDURES OR WHEN THEY SUFFER FROM THROMBOEMBOLISM.	KABIVITRUM, INC. P.O. BOX 430 DANVILLE CA 94526 DD 02/08/85 MA 12/13/89

NAME Generic Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated
TN= Trade Name		MA= Marketing Approval
APROTIMIN	FOR PROPHYLACTIC USE TO REDUCE PERIOPERATIVE	MILES, INC.
TN= TRASLYOL	BLOOD LOSS AND THE HOMOLOGOUS BLOOD TRANSFUSION REQUIREMENT IN PATIENTS UNDERGOING CARDIOPULMONARY BYPASS SURGERY IN THE COURSE OF REPEAT CORONARY ARTERY BYPASS GRAFT SURGERY, AND IN SELECTED CASES OF PRIMARY CORONARY ARTERY BYPASS GRAFT SURGERY WHERE THE RISK OF BLEEDING IS ESPECIALLY HIGH (IMPAIRED HEMOSTASIS) OR WHERE TRANSFUSION IS UNAVAILABLE OR UNACCEPTABLE.	400 MORGAN LANE WEST HAVEN CT 06516 DD 11/17/93 MA 12/29/93
ATOVAQUONE	TREATMENT OF AIDS ASSOCIATED PNEUMOCYSTIS	BURROUGHS WELLCOME COMPANY
TN= MEPRON	CARINII PNEUMONIA (PCP).	3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 09/10/90 MA 11/25/92
BACLOFEN	TREATMENT OF INTRACTABLE SPASTICITY CAUSED BY	MEDTRONIC, INC.
TN= LIORISAL INTRATHECAL	SPINAL CORD INJURY, MULTIPLE SCLEROSIS, AND OTHER SPINAL DISEASES (INCLUDING SPINAL ISCHEMIA, SPINAL TUMOR, TRANSVERSE MYELITIS, CERVICAL SPONDYLOSIS, AND DEGENERATIVE MYELOPATHY).	7000 CENTRAL AVE N.E. MINNEAPOLIS MN 55432 DD 11/10/87 MA 06/25/92
BENZOATE AND PHENYLACETATE	ADJUNCTIVE THERAPY IN THE PREVENTION AND	KENDALL McGAW LABORATORIES
TN= UCEPHAM	TREATMENT OF HYPERAMMONEMIA IN PATIENTS WITH UREA CYCLE ENZYMOPATHY (UCE) DUE TO CARBAMYLPHOSPHATE SYNTHETASE, ORNITHINE, TRANSCARBAMYLASE, OR ARGINOSUCCINATE SYNTHETASE DEFICIENCY.	P.O. BOX 25080 SANTA ANA CA 92799 DD 01/21/86 MA 12/23/87
BERACTANT	TREATMENT OF NEONATAL RESPIRATORY DISTRESS	ROSS LABORATORIES
TN= SURVANTA INTRATRACHEAL SUSPENSION	SYNDROME (RDS).	625 CLEVELAND AVENUE COLUMBUS OH 43215 DD 02/05/86 MA 07/01/91
BERACTANT	PREVENTION OF NEONATAL RESPIRATORY DISTRESS	ROSS LABORATORIES
TN= SURVANTA INTRATRACHEAL SUSPENSION	SYNDROME (RDS).	625 CLEVELAND AVENUE COLUMBUS OH 43215 DD 02/05/86 MA 07/01/91
BOTULINUM TOXIN TYPE A	TREATMENT OF BLEPHAROSPASM ASSOCIATED WITH	ALLERGAN, INC.
TN= OCULINUM	DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE).	2525 DUPONT DRIVE IRVINE CA 92713-9534 DD 03/22/84 MA 12/29/89
BOTULINUM TOXIN TYPE A	TREATMENT OF STRABISMUS ASSOCIATED WITH	ALLERGAN, INC.
TN= OCULINUM	DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE).	2525 DUPONT DRIVE IRVINE CA 92713-9534 DD 03/22/84 MA 12/29/89
CALCITONIN-HUMAN FOR INJECTION	TREATMENT OF SYMPTOMATIC PAGET'S DISEASE OF	CIBA-GEIGY CORPORATION
TN= CIBACALCIN	BONE (OSTEITIS DEFORMANS)	556 MORRIS AVE SUMMIT NJ 07901 DD 01/20/87 MA 10/31/86

NAME Generic Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD = Date Designated
TN = Trade Name		MA = Marketing Approval
CALCIUM ACETATE	TREATMENT OF HYPERPHOSPHOTEMIA IN END STAGE	BRAINTREE LABORATORIES
TN= PHOS-LO	RENAL FAILURE.	60 COLUMBIAN STREET PO BOX 361 BRAINTREE MA 02184 DD 12/22/88 MA 12/10/90
CHEMODIOL	FOR PATIENTS WITH RADIOLOGIC STONES IN WELL	REID-ROWELL, INC.
TN= CHENIX (EXCLUSIVITY EXPIRED)	OPACIFYING GALLBLADDERS, IN WHOM ELECTIVE SURGERY WOULD BE UNDERTAKEN EXCEPT FOR THE PRESENCE OF INCREASED SURGICAL RISK DUE TO SYSTEMIC DISEASE OR AGE.	901 SAWYER ROAD MARIETTA GA 30062 DD 09/21/84 MA 07/28/83
CITRIC ACID, GLUCONO-DELTA-LACTONE AND MAGNESIUM CARBONATE TN= RENACIDIN IRRIGATION	TREATMENT OF RENAL AND BLADDER CALCULI OF THE APATITE OR STRUVITE VARIETY.	UNITED-GUARDIAN, INC. P.O. BOX 2500 SMITHTOWN NY 11787 DD 08/28/89 MA 10/02/90
CLADRIBIN	TREATMENT OF HAIRY CELL LEUKEMIA.	R.W. JOHNSON RESEARCH INSTITUTE
TN= LEUSTATIN INJECTION		ROUTE 202, PO BOX 300 MARTIN NJ 08869-0602 DD 11/15/90 MA 02/26/93
CLOFAZIMINE	TREATMENT OF LEPROMATOUS LEPROSY, INCLUDING	CIBA-GEIGY CORPORATION
TN= LAMPRENE (EXCLUSIVITY EXPIRED)	DAPSONE-RESISTANT LEPROMATOUS LEPROSY AND LEPROMATOUS LEPROSY COMPLICATED BY ERYTHEMA NODOSUM LEPROSUM.	556 MORRIS AVE SUMMIT NJ 07901 DD 06/11/84 MA 12/15/86
COAGULATION FACTOR IX	REPLACEMENT TREATMENT AND PROPHYLAXIS OF THE	ARMOUR PHARMACEUTICAL COMPANY
TN= MONONINE	HEMORRHAGIC COMPLICATIONS OF HEMOPHILIA B.	500 ARCOLA ROAD, P.O. BOX 1200 COLLEGEVILLE PA 19426-0107 DD 06/27/89 MA 08/20/92
COAGULATION FACTOR IX (HUMAN)	FOR USE AS REPLACEMENT THERAPY IN PATIENTS	ALPHA THERAPEUTIC CORPORATION
TN= ALPHANINE	WITH HEMOPHILIA B FOR THE PREVENTION AND CONTROL OF BLEEDING EPISODES, AND DURING SURGERY TO CORRECT DEFECTIVE HEMOSTASIS.	555 VALLEY BLVD LOS ANGELES CA 90032 DD 07/05/90 MA 12/31/90
COLFOSCERIL PALMITATE	PREVENTION OF HYALINE MEMBRANE DISEASE (HMD),	BURROUGHS WELLCOME COMPANY
TN= EXOSURF NEONATAL FOR INTRATRACHEAL SUSPENSION	ALSO KNOWN AS RESPIRATORY DISTRESS SYNDROME (RDS), IN INFANTS BORN AT 32 WEEKS GESTATION OR LESS	3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 10/20/89 MA 08/02/90
COLFOSCERIL PALMITATE	TREATMENT OF ESTABLISHED HYALINE MEMBRANE	BURROUGHS WELLCOME COMPANY
TN= EXOSURF NEONATAL FOR INTRATRACHEAL SUSPENSION	DISEASE (HMD) AT ALL GESTATIONAL AGES	3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 10/20/89 MA 08/02/90
CROMOLYN SODIUM	TREATMENT OF MASTOCYTOSIS.	FISONS CORPORATION
TN= GASTROCROM		755 JEFFERSON RD., PO BOX 1710 ROCHESTER NY 14603 DD 03/08/84 MA 12/22/89
CROMOLYN SODIUM 4% OPHTHALMIC SOLUTION TN= OPTICROM 4% OPHTHALMIC SOLUTION (EXCLUSIVITY EXPIRED)	TREATMENT OF VERNAL KERATOCONJUNCTIVITIS (VKC).	FISONS CORPORATION 755 JEFFERSON RD., PO BOX 1710 ROCHESTER NY 14603 DD 07/24/85 MA 10/03/84

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CYTOMEGALOVIRUS IMMUNE GLOBULIN (HUMAN) TN=	PREVENTION OR ATTENUATION OF PRIMARY CYTOMEGALOVIRUS DISEASE IN IMMUNOSUPPRESSED RECIPIENTS OF ORGAN TRANSPLANTS.	MASS PUB HEALTH BIO LABS 305 SOUTH STREET BOSTON MA 02130 DD 08/03/87 MA 04/17/90
DESMOPRESSIN ACETATE TN= DDAVP HIGH CONCENTRATION (1.5 MG/ML) NASAL SPRAY	TREATMENT OF MILD HEMOPHILIA A AND VON WILLEBRAND'S DISEASE.	RHONE-POULENC RORER PHARM. 500 ARCOLA ROAD COLLEGEVILLE PA 19426 DD 01/22/91 MA 03/07/94
DIGOXIN IMMUNE FAB (OVINE) TN= DIGIBIND (EXCLUSIVITY EXPIRED)	TREATMENT OF POTENTIALLY LIFE THREATENING DIGITALIS INTOXICATION IN PATIENTS WHO ARE REFRACTORY TO MANAGEMENT BY CONVENTIONAL THERAPY.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 11/01/84 MA 03/21/86
DORNASE ALFA TN= PULMOZYME	TO REDUCE MUCOUS VISCOSITY AND ENABLE THE CLEARANCE OF AIRWAY SECRETIONS IN PATIENTS WITH CYSTIC FIBROSIS.	GENENTECH, INC. 460 POINT SAN BRUNO BOULEVARD SOUTH SAN FRANCISCO CA 94080 DD 01/16/91 MA 12/30/93
DROMABINOL TN= MARINOL	FOR THE STIMULATION OF APETITE IN PATIENTS WITH A CONFIRMED DIAGNOSIS OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	UNIMED, INC. 2150 EAST LAKE COOK ROAD BUFFALO GROVE IL 60089 DD 01/15/91 MA 12/22/92
EFLORNITHINE HCL TN= ORNIDYL	TREATMENT OF TRYPANOSOMA BRUCEI GAMBIESE INFECTION (SLEEPING SICKNESS).	MARION MERRELL DOW, INC. PO BOX 9707, MARION PARK DRIVE KANSAS CITY MO 64134-0707 DD 04/23/86 MA 11/28/90
EPOETIN ALFA TN= EPOGEN	TREATMENT OF ANEMIA ASSOCIATED WITH END STAGE RENAL DISEASE(ESRD).	AMGEN, INC. 1840 DEHAVILLAND DRIVE THOUSAND OAKS CA 91320-1789 DD 04/10/86 MA 06/01/89
EPOETIN ALFA TN= EPOGEN	TREATMENT OF ANEMIA ASSOCIATED WITH HIV INFECTION OR HIV TREATMENT.	AMGEN, INC. 1840 DEHAVILLAND DRIVE THOUSAND OAKS CA 91320-1789 DD 07/01/91 MA 12/31/90
ETHANOLAMINE OLEATE TN= ETHAMOLIN	TREATMENT OF PATIENTS WITH ESOPHAGEAL VARICES THAT HAVE RECENTLY BLED, TO PREVENT REBLEEDING.	BLOCK DRUG COMPANY, INC. 257 CORNELISON AVENUE JERSEY CITY NJ 07302 DD 03/22/84 MA 12/12/88
ETIDRONATE DISODIUM TN= DIDROMEL	TREATMENT OF HYPERCALCEMIA OF A MALIGNANCY INADEQUATELY MANAGED BY DIETARY MODIFICATION AND/OR ORAL HYDRATION.	MGI PHARMA, INC. 9900 BREN ROAD EAST, SUITE300E MINNEAPOLIS MN 55343-9667 DD 03/21/86 MA 04/21/87
FELBAMATE TN= FELBATOL	TREATMENT OF LENNOX-GASTAUT SYNDROME.	WALLACE LABORATORIES 301B COLLEGE ROAD EAST PRINCETON NJ 08540 DD 01/24/89 MA 07/29/93

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FLUDARABINE PHOSPHATE	TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA	BERLEX LABORATORIES, INC.
TN= FLUDARA	(CLL), INCLUDING REFRACTORY CLL.	1401 HARBOR BAY PARKWAY ALAMEDA CA 94501-7070 DD 04/18/89 MA 04/18/91
GALLIUM NITRATE INJECTION	TREATMENT OF HYPERCALCEMIA OF MALIGNANCY.	FUJISAWA PHARMACEUTICAL CO.
TN= GANITE		3 PARKWAY NORTH DEERFIELD IL 60015-2548 DD 12/05/88 MA 01/17/91
GONADORELIN ACETATE	INDUCTION OF OVULATION IN WOMEN WITH	R.W.JOHNSON RESEARCH INSTITUTE
TN= LUTREPULSE	HYPOTHALAMIC AMENORRHEA DUE TO A DEFICIENCY OR ABSENCE IN THE QUANTITY OR PULSE PATTERN OF ENDOGENOUS GnRH SECRETION.	ROUTE 202, P.O. BOX 300 RARITAN NJ 08869-0602 DD 04/22/87 MA 10/10/89
HALOFANTRINE	TREATMENT OF MILD TO MODERATE ACUTE MALARIA	SMITHKLINE BEECHAM
TN= HALFAN	CAUSED BY SUSCEPTIBLE STRAINS OF P. FALCIPARUM AND P. VIVAX.	P.O. BOX 1510 KING OF PRUSSIA PA 19406 DD 11/04/91 MA 07/24/92
HEMIN	AMELIORATION OF RECURRENT ATTACKS OF ACUTE	ABBOTT LABORATORIES
TN= PANHEMATIN (EXCLUSIVITY EXPIRED)	INTERMITTENT PORPHYRIA (AIP) TEMPORARILY RELATED TO THE MENSTRUAL CYCLE IN SUSCEPTIBLE WOMEN AND SIMILAR SYMPTOMS WHICH OCCUR IN OTHER PATIENTS WITH AIP, PORPHYRIA VARIEGATA AND HEREDITA COPROPORPHYRIA	DIAGNOSTICS DIVISION ABBOTT PARK IL 60064 DD 03/16/84 MA 07/20/83
HISTRELIN ACETATE	TREATMENT OF CENTRAL PRECOCIOUS PUBERTY.	ROBERTS PHARMACEUTICAL CORP.
TN= SUPPRELIN INJECTION		6 INDUSTRIAL WAY WEST EATONTOWN NJ 07724 DD 08/10/88 MA 12/24/91
IDARUBICIN HCL FOR INJECTION	TREATMENT OF ACUTE MYELOGENOUS LEUKEMIA	ADRIA LABORATORIES, INC.
TN= IDAMYCIN	(AML), ALSO REFERRED TO AS ACUTE NONLYMPHOCYTIC LEUKEMIA (ANLL).	P.O. BOX 16529 COLUMBUS OH 43216-6529 DD 07/25/88 MA 09/27/90
IFOSFAMIDE	IN COMBINATION WITH CERTAIN OTHER APPROVED	BRISTOL-MYERS SQUIBB
TN= IFEX	ANTINEOPLASTIC AGENTS, FOR THIRD LINE CHEMOTHERAPY IN THE TREATMENT OF GERM CELL TESTICULAR CANCER.	5 RESEARCH PARKWAY WALLINGFORD CT 06492-7660 DD 01/20/87 MA 12/30/88
IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	INFECTION PROPHYLAXIS IN PEDIATRIC PATIENTS	MILES, INC.
TN= GAMIMUNE N	AFFECTED WITH THE HUMAN IMMUNODEFICIENCY VIRUS.	4TH & PARKER STREETS BERKELEY CA 94710 DD 02/18/93 MA 12/27/93
INTERFERON ALFA-2A (RECOMBINANT)	TREATMENT OF AIDS RELATED KAPOSI'S SARCOMA.	HOFFMANN-LA ROCHE, INC.
TN= ROFERON-A		340 KINGSLAND STREET NUTLEY NJ 07110 DD 12/14/87 MA 11/21/88
INTERFERON ALFA-2B (RECOMBINANT)	TREATMENT OF AIDS-RELATED KAPOSI'S SARCOMA.	SCHERING CORPORATION
TN= INTRON A		2000 GALLOPING HILL ROAD KENNEDY NJ 07033-2188

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INTERFERON BETA, RECOMBINANT HUMAN TN= BETASERON	TREATMENT OF MULTIPLE SCLEROSIS.	CHIRON CORPORATION 4560 HORTON STREET EMERYVILLE CA 94608 DD 11/17/88 MA 07/23/93
INTERFERON GAMMA 1-B TN= ACTIMMUNE	TREATMENT OF CHRONIC GRANULOMATOUS DISEASE.	GENENTECH, INC. 460 POINT SAN BRUNO BOULEVARD SOUTH SAN FRANCISCO CA 94080 DD 09/30/88 MA 12/20/90
LEUCOVORIN TN= LEUCOVORIN CALCIUM	FOR USE IN COMBINATION WITH 5-FLUOROURACIL FOR THE TREATMENT OF METASTATIC COLORECTAL CANCER.	LEDERLE LABORATORIES DIVISION N. MIDDLETOWN ROAD PEARL RIVER NY 10965 DD 12/08/86 MA 12/12/91
LEUCOVORIN TN= LEUCOVORIN CALCIUM	FOR RESCUE USE AFTER HIGH DOSE METHOTREXATE THERAPY IN THE TREATMENT OF OSTEOSARCOMA	LEDERLE LABORATORIES DIVISION AMERICAN CYANAMID COMPANY PEARL RIVER NY 10965 DD 08/17/88 MA 08/31/88
LEUPROLIDE ACETATE TN= LUPRON INJECTION	TREATMENT OF CENTRAL PRECOCIOUS PUBERTY.	TAP PHARMACEUTICALS, INC. 2355 WAUKEGAN ROAD DEERFIELD IL 60015 DD 07/25/88 MA 04/16/93
LEVOCARNITINE TN= VITA CARN 300 (EXCLUSIVITY EXPIRED)	TREATMENT OF GENETIC CARNITINE DEFICIENCY.	SIGMA-TAU PHARMACEUTICALS, INC. 200 ORCHARD RIDGE DRIVE, SUITE GAITHERSBURG MD 20878-1978 DD 02/28/84 MA 04/10/86
LEVOCARNITINE TN= CARNITOR 300 (EXCLUSIVITY EXPIRED)	TREATMENT OF PRIMARY CARNITINE DEFICIENCY OF GENETIC ORIGIN.	SIGMA-TAU PHARMACEUTICALS, INC. 200 ORCHARD RIDGE DRIVE, SUITE GAITHERSBURG MD 20878-1978 DD 07/26/84 MA 12/27/85
LEVOCARNITINE TN= CARNITOR 300	TREATMENT OF SECONDARY CARNITINE DEFICIENCY OF GENETIC ORIGIN.	SIGMA-TAU PHARMACEUTICALS, INC. 200 ORCHARD RIDGE DRIVE, SUITE GAITHERSBURG MD 20878-1978 DD 07/26/84 MA 12/16/92
LEVOMETHADYL ACETATE HYDROCHLORIDE 300 TN= ORLAAM	TREATMENT OF HEROIN ADDICTS SUITABLE FOR MAINTENANCE ON OPIATE AGONISTS.	BIODEVELOPMENT CORPORATION 1300 NORTH 17th STREET, SUITE ARLINGTON VA 22209-2306 DD 01/24/84 MA 07/09/93
LIOTHYRONINE SODIUM INJECTION TN= TRIOSTAT	TREATMENT OF MYXEDEMA COMA/PRECOMA.	SMITHKLINE BEECHAM P.O. BOX 1510 KING OF PRUSSIA PA 19406 DD 07/30/90 MA 12/31/91

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LODOXAMIDE TROMETHAMINE TN= ALONIDE OPHTHALMIC SOLUTION	TREATMENT OF VERNAL KERATOCONJUNCTIVITIS.	ALCON LABORATORIES, INC. 6201 SOUTH FREEWAY FORT WORTH TX 76134 DD 10/16/91 MA 09/23/93
MEFLOQUINE HCL TN= LARIAM	TREATMENT OF ACUTE MALARIA DUE TO PLASMODIUM FALCIPARUM AND PLASMODIUM VIVAX.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND STREET NUTLEY NJ 07110 DD 04/13/88 MA 05/02/89
MEFLOQUINE HCL TN= LARIAM	PROPHYLAXIS OF PLASMODIUM FALCIPARUM FALCIPARUM MALARIA WHICH IS RESISTANT TO OTHER AVAILABLE DRUGS.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND STREET NUTLEY NJ 07110 DD 04/13/88 MA 05/02/89
MEGESTROL ACETATE TN= MEGACE	TREATMENT OF PATIENTS WITH ANOREXIA, CACHEXIA, OR SIGNIFICANT WEIGHT LOSS ($\geq 10\%$ OF BASELINE BODY WEIGHT) AND CONFIRMED DIAGNOSIS OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	BRISTOL-MYERS SQUIBB 2400 WEST LLOYD EXPRESSWAY EVANSVILLE IN 47721-0001 DD 04/13/88 MA 09/10/93
MELPHALAN TN= ALKERAN FOR INJECTION	TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA FOR UNION ORAL THERAPY IS INAPPROPRIATE.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 02/24/92 MA 11/18/92
MESNA TN= MESNEX	FOR USE AS A PROPHYLACTIC AGENT IN REDUCING THE INCIDENCE OF IFOSFAMIDE-INDUCED HEMORRHAGIC CYSTITIS.	DEGUSSA CORPORATION 65 CHALLENGER ROAD RIDGEFIELD PARK NJ 07660 DD 11/14/88 MA 12/30/88
METHOTREXATE SODIUM TN= METHOTREXATE	TREATMENT OF OSTEOGENIC SARCOMA.	LEDERLE LABORATORIES DIVISION AMERICAN CYANAMIDE COMPANY PEARLE RIVER NY 10965 DD 10/21/85 MA 04/07/88
METRONIDAZOLE (TOPICAL) TN= METROGEL	TREATMENT OF ACNE ROSACEA	CURATEK PHARMACEUTICALS 1965 PRATT BLVD. ELK GROVE VILLAGE IL 60007 DD 10/22/87 MA 11/22/88
MITOXANTRONE HCL TN= NOVANTRONE	TREATMENT OF ACUTE MYELOGENOUS LEUKEMIA (AML), ALSO REFERRED TO AS ACUTE NONLYMPHOCTIC LEUKEMIA (ANLL).	LEDERLE LABORATORIES DIVISION AMERICAN CYANAMIDE COMPANY PEARL RIVER NY 10965 DD 07/13/87 MA 12/23/87
MONOOCETANOIN TN= MOCTANIN (EXCLUSIVITY EXPIRED)	DISSOLUTION OF CHOLESTEROL GALLSTONES RETAINED IN THE COMMON BILE DUCT.	ETHITEK PHARMACEUTICALS, INC. 8100 NORTH LAWNDALE AVE. SKOKIE IL 60076 DD 05/30/84 MA 10/31/85
MORPHINE SULFATE CONCENTRATE (PRESERVATIVE FREE) TN= INFUMORPH	FOR USE IN MICROINFUSION DEVICES FOR INTRASPINAL ADMINISTRATION IN THE TREATMENT OF INTRACTABLE CHRONIC PAIN.	ELKINS-SINN, INC. 2 ESTERBROOK LANE CHERRY HILL NJ 08003-4099 DD 07/12/90 MA 07/19/91

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MAFARELIN ACETATE	TREATMENT OF CENTRAL PRECOCIOUS PUBERTY	SYNTEX (USA), INC.
TN= SYMAREL NASAL SOLUTION (WAIVED EXCLUSIVITY)		3401 HILLVIEW AVENUE PALO ALTO CA 94303 DD 07/20/88 MA 02/26/92
MALTREXONE HCL	BLOCKADE OF THE PHARMACOLOGICAL EFFECTS OF	DU PONT PHARMACEUTICALS
TN= TREXAN (EXCLUSIVITY EXPIRED)	EXOGENOUSLY ADMINISTERED OPIOIDS AS AN ADJUNCT TO THE MAINTENANCE OF THE OPIOID-FREE STATE IN DETOXIFIED FORMERLY OPIOID-DEPENDENT INDIVIDUALS.	E.I. du PONT de NEMOURS & CO. WILMINGTON DE 19880-0026 DD 03/11/85 MA 11/30/84
PEGADENASE BOVINE	ENZYME REPLACEMENT THERAPY FOR ADA DEFICIENCY	ENZON, INC.
TN= ADAGEN	IN PATIENTS WITH SEVERE COMBINED IMMUNODEFICIENCY (SCID).	40 KINGSBRIDGE ROAD PISCATAWAY NJ 08854-3998 DD 05/29/84 MA 03/21/90
PEGASPARGASE	TREATMENT OF ACUTE LYMPHOBLASTIC LEUKEMIA	ENZON, INC.
TN= ONCASPAR	(ALL).	40 KINGSBRIDGE ROAD PISCATAWAY NJ 08854-3998 DD 10/20/89 MA 02/01/94
PENTAMIDINE ISETHIONATE	TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA.	FUJISAMA PHARMACEUTICAL CO.
TN= PENTAM 300 (EXCLUSIVITY EXPIRED)		3 PARKWAY NORTH DEERFIELD IL 60015-2548 DD 02/28/84 MA 10/16/84
PENTAMIDINE ISETHIONATE	PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA	FUJISAMA PHARMACEUTICAL CO.
TN= NEBUPENT	IN PATIENTS AT HIGH RISK OF DEVELOPING THIS DISEASE.	3 PARKWAY NORTH DEERFIELD IL 60015-2548 DD 01/12/88 MA 06/15/89
PENTASTARCH	ADJUNCT IN LEUKAPHERESIS TO IMPROVE THE	DU PONT PHARMACEUTICALS
TN= PENTASPAR	HARVESTING AND INCREASE THE YIELD OF LEUKOCYTES BY CENTRIFUGAL MEANS.	E.I. du PONT de NEMOURS & CO. WILMINGTON DE 19898 DD 08/28/85 MA 05/19/87
PENTOSTATIN FOR INJECTION	TREATMENT OF HAIRY CELL LEUKEMIA.	WARNER-LAMBERT COMPANY
TN= NIPENT		2800 PLYMOUTH RD., PO BOX 1047 ANN ARBOR MI 48106 DD 09/10/87 MA 10/11/91
PILOCARPINE HCL	TREATMENT OF XEROSTOMIA INDUCED BY RADIATION	MGI PHARMA, INC.
TN= SALAGEN	THERAPY FOR HEAD AND NECK CANCER.	SUITE 300 E, 9900 BREN ROAD EAST MINNEAPOLIS MN 55343-9667 DD 09/24/90 MA 03/22/94
POTASSIUM CITRATE	PREVENTION OF URIC ACID NEPHROLITHIASIS.	UNIV. OF TEXAS HEALTH SCIENCES
TN= UROCIT-K (EXCLUSIVITY EXPIRED)		5323 HARRY HINES BLVD DALLAS TX 75235 DD 11/01/84 MA 08/30/85
POTASSIUM CITRATE	PREVENTION OF CALCIUM RENAL STONES IN	UNIV. OF TEXAS HEALTH SCIENCES
TN= UROCIT-K (EXCLUSIVITY EXPIRED)	PATIENTS WITH HYPOCITRATURIA.	5323 HARRY HINES BLVD DALLAS TX 75235 DD 09/16/85 MA 08/30/85

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POTASSIUM CITRATE	AVOIDANCE OF THE COMPLICATION OF CALCIUM	UNIV. OF TEXAS HEALTH SCIENCES
TN= UROCIT K (EXCLUSIVITY EXPIRED)	STONE FORMATION IN PATIENTS WITH URIC LITHIASIS.	5323 HARRY HINES BLVD. DALLAS TX 75235 DD 05/29/84 MA 08/30/85
RIFABUTIN	PREVENTION OF DISSEMINATED MYCOBACTERIUM	ADRIA LABORATORIES, INC.
TN= MYCOBUTIN	AVIUM COMPLEX (MAC) DISEASE IN PATIENTS WITH ADVANCED HIV INFECTION.	P.O. BOX 16529 COLUMBUS OH 43216-6529 DD 12/18/89 MA 12/23/92
RIFAMPIN	ANTITUBERCULOSIS TREATMENT WHERE USE OF THE	MARION MERRELL DOW, INC.
TN= RIFADIN I.V.	ORAL FORM OF THE DRUG IS NOT FEASIBLE.	PO BOX 9707, MARION PARK DRIVE KANSAS CITY MO 64134-0707 DD 12/09/84 MA 05/25/89
SARGRAMOSTIM	TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE	IMMUNEX CORPORATION
TN= LEUKINE	MARROW TRANSPLANT IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE, AND ACUTE LYMPHOBLASTIC LEUKEMIA.	51 UNIVERSITY STREET SEATTLE WA 98101 DD 05/03/90 MA 03/05/91
SARGRAMOSTIM	TREATMENT OF PATIENTS WHO HAVE UNDERGONE	IMMUNEX CORPORATION
TN= LEUKINE	ALLOGENEIC OR AUTOLOGOUS BONE MARROW TRANSPLANTATION AND IN WHOM ENGRAFTMENT IS DELAYED OR IN WHOM ENGRAFTMENT FAILS.	51 UNIVERSITY STREET SEATTLE WA 98101 DD 05/03/90 MA 12/31/91
SATUMOMAB PENDETIDE	DETECTION OF OVARIAN CARCINOMA.	CYTOGEN CORPORATION
TN= ONCOSCINT CR/OV		201 COLLEGE ROAD EAST PRINCETON NJ 08540-5308 DD 09/25/89 MA 12/29/92
SELEGILINE HCL	ADJUVANT TO LEVODOPA AND CARBIDOPA TREATMENT	SOMERSET PHARMACEUTICALS, INC.
TN= ELDEPRYL	OF IDIOPATHIC PARKINSON'S DISEASE (PARALYSIS AGITANS), POSTENCEPHALITIC PARKINSONISM, AND SYMTOMATIC PARKINSONISM.	400 MORRIS AVENUE, SUITE 75 DENVER NJ 07854 DD 11/07/84 MA 06/05/89
SOMATREM FOR INJECTION	FOR LONG-TERM TREATMENT OF CHILDREN WHO HAVE	GENENTECH, INC.
TN= PROTROPIN (EXCLUSIVITY EXPIRED)	GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION.	460 POINT SAN BRUNO BOULEVARD SOUTH SAN FRANCISCO CA 94080 DD 12/09/85 MA 10/17/85
SOMATROPIN FOR INJECTION	LONG-TERM TREATMENT OF CHILDREN WHO HAVE	ELI LILLY AND COMPANY
TN= HUMATROPE (EXCLUSIVITY EXPIRED)	GROWTH FAILURE DUE TO INADEQUATE SECRETION OF NORMAL ENDOGENOUS GROWTH HORMONE.	LILLY CORPORATE CENTER INDIANAPOLIS IN 46285 DD 06/12/86 MA 03/08/87
SOMATROPIN FOR INJECTION	TREATMENT OF GROWTH RETARDATION ASSOCIATED	GENENTECH, INC.
TN= NUTROPIN	WITH CHRONIC RENAL FAILURE.	460 POINT SAN BRUNO BOULEVARD SOUTH SAN FRANCISCO CA 94080 DD 08/04/89 MA 11/17/93
SOTALOL HCL	TREATMENT OF LIFE-THREATENING VENTRICULAR	BERLEX LABORATORIES
TN= BETAPACE	TACHYARRHYTHMIAS.	300 FAIRFIELD ROAD WAYNE, NJ 07470-4100 DD 09/23/88 MA 10/30/92

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SUCCIMER	TREATMENT OF LEAD POISONING IN CHILDREN.	MCNEIL CONSUMER PRODUCTS CO.
TN= CHEMET CAPSULES		CAMP HILL ROAD FORT WASHINGTON PA 19034 DD 05/09/84 MA 01/30/91
TENIPOSIDE	TREATMENT OF REFRACTORY CHILDHOOD ACUTE	BRISTOL-MYERS SQUIBB
TN= VUNON FOR INJECTION	LYMPHOCTIC LEUKEMIA (ALL).	5 RESEARCH PARKWAY WALLINGFORD CT 06492-7660 DD 11/01/84 MA 07/14/92
TERIPARATIDE	DIAGNOSTIC AGENT TO ASSIST IN ESTABLISHING	RHONE-POULENC RORER PHARM.
TN= PARATHAR	THE DIAGNOSIS IN PATIENTS PRESENTING WITH CLINICAL AND LABORATORY EVIDENCE OF HYPOCALCEMIA DUE TO EITHER HYPOPARATHYROIDISM OR PSEUDOHYPOPARATHYROIDISM.	500 ARCOLA ROAD COLLEGEVILLE PA 19426 DD 01/09/87 MA 12/23/87
TIOPRONIN	PREVENTION OF CYSTINE NEPHROLITHIASIS IN	PAX, CHARLES Y.C. M.D.
TN= THIOLA	PATIENTS WITH HOMOZYGOUS CYSTINURIA.	5323 HARRY HINES BOULEVARD DALLAS TX 75235 DD 01/17/86 MA 08/11/88
TRAMEXAMIC ACID	TREATMENT OF PATIENTS WITH CONGENITAL	KABIVITRUM, INC.
TN= CYKLOKAPRON (EXCLUSIVITY EXPIRED)	COAGULOPATHIES WHO ARE UNDERGOING SURGICAL PROCEDURES E.G. DENTAL EXTRACTIONS.	P.O. BOX 262069 SAN DIEGO CA 92196 DD 10/29/85 MA 12/30/86
TRIENTINE HCL	TREATMENT OF PATIENTS WITH WILSON'S DISEASE	MERCK SHARP & DOWNE RESEARCH
TN= CUPRID (EXCLUSIVITY EXPIRED)	WHO ARE INTOLERANT, OR INADEQUATELY RESPONSIVE TO PENICILLAMINE.	DIVISION OF MERCK AND COMPANY WEST POINT PA 19486 DD 12/24/84 MA 11/08/85
TRIMETREXATE GLUCURONATE	TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA	U.S. BIOSCIENCE, INC.
TN= NEUTREXIN STREET	IN AIDS PATIENTS.	ONE TOWER BRIDGE, 100 FRONT WEST CONSHOHOCKEN PA 19428 DD 05/15/86 MA 12/17/93
UROFOLLITROPIN	INDUCTION OF OVULATION IN PATIENTS WITH	SERONO LABORATORIES, INC.
TN= METRODIN (EXCLUSIVITY EXPIRED)	POLYCYSTIC OVARIAN DISEASE WHO HAVE AN ELEVATED LH/FSH RATIO AND WHO HAVE FAILED TO RESPOND TO ADEQUATE CLONIPHENE CITRATE THERAPY.	100 LONGWATER CIRCLE NORWELL MA 02061 DD 11/25/87 MA 09/18/86
ZALCITABINE	TREATMENT OF ACQUIRED IMMUNODEFICIENCY	HOFFMANN-LA ROCHE, INC.
TN= NIVID	SYNDROME (AIDS).	340 KINGSLAND STREET MUTLEY NJ 07110-1199 DD 06/28/88 MA 06/19/92
ZIDOVUDINE	TREATMENT OF ACQUIRED IMMUNODEFICIENCY	BURROUGHS WELLCOME COMPANY
TN= RETROVIN (EXCLUSIVITY EXPIRED)	SYNDROME (AIDS).	3030 CORMMALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 07/17/85 MA 03/19/87
ZIDOVUDINE	TREATMENT OF AIDS RELATED COMPLEX (ARC).	BURROUGHS WELLCOME COMPANY
TN= RETROVIN (EXCLUSIVITY EXPIRED)		3030 CORMMALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 05/12/87 MA 03/19/87

ORPHAN GRANTS AND CONTRACTS

Mr. DURBIN. Please provide a listing of all grants and contracts issued during fiscal year 1993 for orphan product work.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

**Office of Orphan Products Development
Grant Awards - FY 93**

Botulism Immune Globulin for Infant Botulism

California Department of Health Services, Berkeley, California
Stephen S. Arnon, M.D.

Maintenance Therapy of Wilson's Disease with Zinc

University of Michigan, Ann Arbor, Michigan
George J. Brewer, M.D.

Clinical Trial of Polyvalent Antigen Vaccine for Melanoma

New York University Medical Center, New York, New York
Jean-Claude Bystryn, M.D.

Inhaled Steroid for Improvement of Newborn Lung Function

New England Medical Center, Boston, Massachusetts
Cynthia H. Cole, M.D.

Clinical Trial of Polyspecific Crotalid Antivenin

Therapeutic Antibodies, Inc., Nashville, Tennessee
Richard Charles Dart, M.D., Ph.D.

L-baclofen in Trigeminal Neuralgia

University of Pittsburgh, Pittsburgh, Pennsylvania
Gerhard H. Fromm, M.D.

TGF-B2 for the Treatment of Macular Holes

Celtrix Pharmaceuticals, Inc., Santa Clara, California
Ann F. Hanham, Ph.D.

Phase I Study of DMSA in Familial Amyloidosis

Columbia University College of Physicians and Surgeons, New York,
New York
Joseph Herbert, M.D.

Evaluation of Naltrexone in Autistic Children

Children's Hospital National Medical Center, Washington, DC
Andrew Levy, Ph.D.

Methotrexate-Azone Gel in Mycosis Fungoides

McGill University, Montreal Quebec
Brian Reginald Leyland-Jones, M.D.

Safety & Pharmacology of Tretinoin FL IV in Leukemia Patients

University of Texas M.D. Anderson Cancer Center, Houston, Texas
Kapil Mehta, Ph.D.

Piracetam for Pediatric Myoclonus: Efficacy and Safety

Children's National Medical Center, Washington, DC
Michael R. Pranzatelli, M.D.

Clinical Trial of Zinc in Sickle Cell Anemia

Wayne State University, Detroit, Michigan
Ananda S. Prasad, M.D., Ph.D.

Treatment of Gh Receptor Deficient Children with IGF-I

Kabi Pharmacia, Inc., Piscataway, New Jersey
Magnus Precht

Glutathione Monoethyl Ester Therapy of 5-Oxoprolinuria

University of Iowa, Iowa City, Iowa
William J. Rhead, M.D., Ph.D.

Anti-Cd-33 in Relapsed APL

Sloan-Kettering Institute for Cancer Research, New York, New York
David A. Scheinberg, M.D., Ph.D.

Recombinant Human Growth Hormone in Renal Failure

Vanderbilt University Medical Center, Nashville, Tennessee
Gerald Schulman, M.D.

Hormonal Regulation of Infantile Hemangiomas

Children's Hospital Corporation, Boston, Massachusetts
Lois Hodgson Smith, M.D., Ph.D.

Growth Hormone in Short Bowel Patients

Brigham & Women's Hospital, Boston, Massachusetts
Douglas Wayne Wilmore, M.D.

Phase II Trial of CH14.18 & GM-CSF in Neuroblastoma

University of California, San Diego, La Jolla, California
Alice L. Yu, M.D., Ph.D.
Unfunded Orphan Product Grants

Mr. DURBIN. How many requests for grants related to orphan products do you have on hand that are unfunded?

Dr. KESSLER. There are approximately 34 approved but unfunded applications pending from the last review cycle. The FY 94 grant review process is currently in progress. We expect approximately 40 applications from the current review cycle to be approved but unfunded, bringing the total to approximately 74.

COST TO FUND ALL ORPHAN GRANTS

Mr. DURBIN. What is the total needed to fund all these grants?

Dr. KESSLER. The total needed to fund the 74 pending applications is approximately \$9.3 million.

NEW DRUG APPLICATIONS

Mr. DURBIN. How many NDA's are currently pending before FDA and of those, how many have been pending for more than 180 days?

Dr. KESSLER. As of January 31, 1994, there were 155 pending NDA's. Of these, 47 were pending for more than 180 days.

ABBREVIATED NEW DRUG APPLICATIONS

Mr. DURBIN. How many ANDA's are currently pending at FDA and of those, how many have been pending for more than 180 days?

Dr. KESSLER. At the end of fiscal year 1993, there were 485 generic drug applications—AADA's and ANDA's—pending. Of the 485 pending generic drug applications, 24 ANDA's were pending more than 180 days.

FOOD LABELING

Mr. DURBIN. What do you anticipate spending on food labeling issues during fiscal year 1994?

Dr. KESSLER. The Agency anticipates spending approximately \$6 million on food labeling activities in FY 1994. This number is based on actual resource utilization so far in FY 1994 and is lower than estimates made earlier which assumed we would receive a larger number of petitions than we have.

EMERGENCY FUND

Mr. DURBIN. For the last couple of years, the Committee has provided \$2 million to go into FDA's special or emergency fund. What is the current status of that fund?

Dr. KESSLER. FDA has a balance of \$3.7 million in the contingency fund. This includes \$2.0 million from FY 1991 appropriations and \$1.7 million from FY 1990 appropriations.

Mr. DURBIN. Also describe for us the individual occurrences where you used the fund in the past year.

Dr. KESSLER. FDA has not used the contingency fund since 1992 when \$351,000 was used to support the Breast Implant emergency.

FOOD SURVEILLANCE

Mr. DURBIN. Every year FDA responds to several special assignments related to food surveillance. For the record, please provide us a list of each of these.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

FOOD SURVEILLANCE

In FY 93 FDA issued 27 special assignments to augment information on food products gathered under our compliance programs. These assignments were issued to multiple field districts and are in addition to specific assignments issued to obtain additional evidence or regulatory information concerning specific firms regulated by the Agency.

1. Dried Seafood Collection Assignment.
2. *Vibrio cholerae* in Domestic and Imported Foods.
3. Chloramphenicol in Imported and Domestic Shrimp.
4. Sampling of By-Product HCL Produced by Freon Manufacturing Process.
5. Possible Misbranding of Grain Fiber.
6. Methyl Mercury in Imported and Domestic Shark, Swordfish, Canned & Fresh Tuna.
7. Import Metal Can Assignment.
8. Domestic and Import Breaded Shrimp.
9. Domestic and Import Raw Scallops.
10. Glandular and/or Neural Tissue Derived Product.
11. Lead & Cadmium in Domestic and Imported Seafood.
12. Oxolinic Acid in Imported Salmon.
13. Retail Sampling Assignment—Sweet Corn & Apple Juice.
14. Retail Survey & Sample Trace-back—Chaparral Containing Products.
15. Selected Fishery Products.
16. New Zealand Strawberries.
17. Canned Tuna Market Survey—Domestic and Import.
18. Rodent Infestation on Passenger Train Survey.
19. Collection, Analysis, and Product Information of Select Dietary Supplements.
20. Tuna Cannery Inspection.
21. Contract Packagers—Canned Seafood.
22. Chicken-of-the-Sea Canned Tuna.
23. Vitamin A & D Fortification of Milk.
24. Multiple Food Warehouse Inspection.
25. Radionuclides In Imported Fishery Products from the Arctic.
26. Color Manufacture Inspection.
27. Salmonella in Dried Infant Formula & Medical Food Products.

CHINESE MUSHROOMS

Mr. DURBIN. In February of this year FDA seized approximately \$30,000 worth of canned mushrooms because a sample contained staphylococcal enterotoxin and another group was seized because of misbranding. Were both these cases caught because of detention on Chinese mushrooms.

Dr. KESSLER. These two lots were not caught because of the Chinese mushroom detentions since they were labeled and invoiced as product of Taiwan and Thailand. We later determined that these lots had been processed in the Peoples Republic of China, following receipt of an industry report that staphylococcal enterotoxin was found in mushrooms labeled as product of Taiwan.

The \$30,000 lot labeled as product of Taiwan was in domestic commerce when we determined it was fraudulently labeled. Five lots of the same brand have been found and three have already been seized. Three of the these lots were caught at the port of entry after we placed the "reported" Taiwan manufacturer under auto-

matic detention. A sample of the \$30,000 lot was analyzed by FDA and two additional production code lots were found to contain staphylococcal enterotoxin.

The seized lot which was misbranded was labeled as a product of Thailand, was caught at the port of entry during routine review of entry documents and an examination of the lot. Our experience with the fraudulent Taiwan situation and knowledge of certain factory's can coding system helped us identify this fraudulent entry as from the People's Republic of China.

Mr. DURBIN. Are canned mushrooms from China still on your automatic detention list?

Dr. KESSLER. Yes. Import Alert 25-11, which was revised on November 16, 1993, entitled "Automatic Detention of Canned and Brined Mushrooms from the Peoples Republic of China" directs the automatic detention of canned mushrooms. All styles, and all container sizes manufactured in the Peoples Republic of China are automatically detained except for straw and oyster mushrooms and brined mushrooms packed in bulk containers.

Some factories are allowed to ship canned mushrooms to the U.S. after documenting that they have identified all potential sources of contamination with staphylococcal enterotoxin, developed procedures and practices to eliminate or control those sources, complied with the significant requirements of the low-acid canned food regulations and is able to assure that production lots entering the U.S. have been processed by the factory.

Once this program appears to be acceptable, we release each entry at the ports. This release is not given until we have a report from a third party—normally a firm which has developed the program and is responsible for monitoring it—that certain processing records have been reviewed and each production lot has been processed properly.

FOOD RECALLS

Mr. DURBIN. Please provide a table showing the number of food products that were recalled or claimed through seizure during fiscal years 1991, 1992, and 1993.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

FOOD PRODUCTS

	Fiscal year—		
	1991	1992	1993
Recalled	559	557	657
Seizures	66	86	47

MEDICAL DEVICE MALFUNCTIONS

Mr. DURBIN. Last year you indicated that medical device malfunctions and faulty product designs were beginning to become a major area of concern for FDA. You described several initiatives that FDA was taking to address the situation. Please update us on

the activity taking place this past year. How many actions have taken place compared to previous years?

Dr. KESSLER. Regulatory actions taken by FDA decreased during the year, down from 1,923 actions in FY 92 to 1,429 actions in FY 93. The types of actions taken include warning letters, seizures, recalls, injunctions and prosecutions. The decrease in number of actions can be attributed to better industry compliance with Good Manufacturing Practices and to industry's increased knowledge of the regulations regarding premarket notification submissions, thereby reducing the number of warning letters issued. I will supply additional details for the record.

[The information follows:]

Since FY 90, there has been a consistent reduction in the average case processing and review times due to more efficient internal procedures and increased communications between headquarters compliance staff and FDA field offices during the investigational stage of case development. Processing time for warning letters decreased from 31 days in FY 92 to 22 days in FY 93 and prosecution recommendations decreased from 35 to 28 days during the same period. The average case processing time for other regulatory actions has remained constant. I will provide information on the number of actions for the record.

[The information follows:]

Medical Device Malfunctions

NUMBER OF ACTIONS	
FY 90	1,040
FY 91	1,410
FY 92	1,923
FY 93	1,429

FDA is using the following activities to address the problem of medical device malfunctions and faulty product design.

- On November 23, 1993, FDA published in the *Federal Register* a proposed rule for medical device GMPs, which incorporates the new design validation requirements of the Safe Medical Devices Act of 1990 (SMDA).
- FDA continues to use the "reference list" to ensure that every premarket notification submission 510(k) processed by FDA is manufactured at a facility in compliance with GMPs.
- FDA uses "industry letters" to inform device manufacturers of recent policy decisions, to explain various procedures (such as export procedures), and to notify industry where to go for further information.
- FDA is developing a policy for the use of the civil penalty provisions of SMDA to ensure that cases will be documented properly and the provisions applied consistently.
- FDA piloted a reorganization of the Office of Compliance which will allow each product-oriented branch to develop a high level of expertise and understanding of specific devices, resulting in a more direct approach to device problems.

- FDA has put the medical device industry on notice that it will take action in cases where corrections have not been made after an acceptable length of time through the initiation of a "corporate-wide" approach to inspections and legal actions for selected firms.

In FY 93 and the first part of FY 94, FDA strengthened its enforcement posture through the following actions:

- Increased focus on multi-site corporate compliance efforts to determine whether manufacturing problems are isolated or rampant throughout the corporation.
- Obtained consent decrees from three manufacturers (National Medical Care, Inc., Physio-Control Corporation, and Puritan-Bennett Corporation) to correct long-term, recurring manufacturing deficiencies. These orders resulted in an immediate shutdown of several facilities at the Physio-Control and Puritan-Bennett Corporations. The action against Puritan-Bennett was the first corporate-wide injunction against a medical device manufacturer for GMP and MDR--medical device reporting--violations.
- Signed a consent decree with the Siemens Corporation on February 10, 1994, and filed the decree with the court on February 24, 1994 because of GMP violations.
- Levied \$61 million in civil penalties and criminal fines against C.R. Bard, Inc. for violations regarding its cardiac catheters, design changes, and adverse effects reporting. This case involved the largest health care fraud investigation in the history of FDA and the Department of Justice.
- Assessed the first civil penalty fines against three device manufacturers for distributing medical devices without 510(k)s or PMAs.

510(K) APPLICATIONS

Mr. DURBIN. How many 510(k) applications are on hand? How many are overdue?

Mr. KESSLER. As of January 31, 1994, FDA had 4,980 pending 510(k) applications. Of those, 1,364 are on hold—in the hands of the manufacturer—and 3,616 are under review—in the hands of the Agency. For those under review, 696 were in house for less than 30 days; 633 for 31–60 days; 463 for 61–90 days; and 1,834 were “overdue” having exceeded the historical 90-day limit for review.

The existence of overdue 510(k) applications is a relatively recent occurrence. At the end of FY 91, and for the preceding five fiscal years, there were no overdue 510(k)s. At the end of FY 92 there were 331 overdue 510(k)s. At the end of FY 92 there were 331 overdue 510(k)s, and this grew to 1,894 by the end of FY 93.

There are several reasons for this growth in overdue applications. In FY 93, FDA received 6,288 510(k)s while completing 5,073. This compares to 6,509 receipts and 4,862 completions in FY 92. Even though the receipts dropped by about 200, and completions increased by about 200, FDA still fell behind by over 1,200 applications in FY 93.

In FY 94, receipts are projected to be very near 6,000. FDA expects application receipts to remain at high levels—four of the top ten fastest growing U.S. industries, according to the 1994 Industrial Outlook, are medical device industries. In recent months, FDA has hired additional reviewers for the device evaluation process, and the results of the first four months of FY 94 finally show an excess of completions over receipts—2,169 completed in the first four months vs. 1,952 received. Not only are there more applications, the submissions have increased in size and complexity. Applications for 501(k) now contain three times as many pages as they did in 1983.

Device reviewers are now required to provide more documentation of their decision on a 510(k) application, thereby increasing review times; they have to review safety and efficacy summaries or the certification that the sponsor will make such summary available; they need to determine if the device is subject to postmarket surveillance; and determine if the sponsor is in violation of Good Manufacturing Practices regulations.

The FY 92, FDA's device evaluation program experienced unprecedented levels of oversight activities from within FDA, HHS, and the Congress. FDA estimates that about 7 to 8 percent of device evaluation resources were diverted in FY 92 to oversight and special concerns over breast implants.

The net effect of FDA continuing to receive more applications than it has been able to compete for the last couple years, the applications being more complex, and some resources being drained away, led to the number of pending applications peaking at over 5,260 at the end of August 1993.

Adding more resources, the implementation of certain new management initiatives such as triaging applications based on risk, a refuse to file policy, and the use of a pilot review process in one

division that increases the delegation of decision-making, has brought the level of pending applications back down under 5,000.

MEDICAL DEVICE EXPENDITURES

Mr. DURBIN. Please provide a five-year table showing the expenditure for medical devices.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

Expenditures for Medical Devices

[Dollars in thousands]

Fiscal year:	
1991	\$104,778
1992	116,731
1993	129,025
1994 estimate	153,314
1995 estimate	177,314

TAMPERING COMPLAINTS

Mr. DURBIN. In the past several years food and drug tampering made headlines across the country. For the record, please provide an updated table that reflects the emergency tampering complaints and threats for each of the past five years.

Dr. KESSLER. I will be happy to provide this information for the record:

[The information follows:]

Tampering Complaints—1989–1993

Year:	Number of complaints
1989	380
1990	154
1991	307
1992	227
1993	470

FREEDOM OF INFORMATION

Mr. DURBIN. How many requests did you receive during fiscal years 1991, 1992, and 1993 for Freedom of Information related activities

Dr. KESSLER. In FY 1993, FDA received 47,978 requests for freedom of information related activities; in FY 1992, 46,501 requests, and in FY 1991, 41,714 requests.

Mr. DURBIN. What resources did you expend on Freedom of Information activities in each of those years?

Dr. KESSLER. In 1993, the total expenditures for Freedom of Information activities were \$7,350,096, in FY 1992, \$7,263,959, and in FY 1991, \$6,311,218.

TRAINING FDA PERSONNEL

Mr. DURBIN. There has been some discussions in the past about using NCTR as training center for FDA personnel. Is this still under consideration?

Dr. KESSLER. NCTR's physical plant and central U.S. location provide FDA a good locale for investigator technical training.

NCTR scientists participate in numerous educational programs and have proven an impressive ability to locate, train, and mentor teachers, students and postdoctoral candidates through diverse special employee appointment programs. In FY 93, NCTR hosted 245 individuals who participated in research, development, and training.

LONG TERM STRATEGIC PLAN FOR TRAINING

Mr. DURBIN. Does FDA have a long term strategic plan for training personnel?

Dr. KESSLER. FDA's draft Strategic Plan includes the long-term plan for training personnel. FDA plans to implement a multi-level career development program which includes training of new employees and the professional development of current employees. The draft plan calls for the centralized development and delivery of Agencywide supervisory and management training, information systems training, and generic skills training, including training administrative officers and others throughout the Agency in how to get maximum benefit from re-engineered and automated administrative processes. The unique technical and scientific training needs of the various Centers and Offices will be met through organizational "Staff Colleges" and/or other decentralized training management activities.

I will provide details of the Agency wide plan for the record.

[The information follows:]

As part of the Agencywide initiative to enhance supervisory and management skills, we established the F.A.M.E. program—Formula for Achieving Managerial Excellence—to provide training and developmental opportunities for supervisors and managers. Currently, the curriculum includes six workshops: Team Building, Communication, Motivation, Leadership, Managing Change, and Career Management. We are piloting the "Introduction to Supervision at FDA" course along with several innovative job aids to assist supervisors with the administrative and personnel aspects of their job.

Over the next several years, we will bring on-line new courses and activities identified in a recent Agencywide training needs analysis. The F.A.M.E. program will ultimately include training courses and other developmental activities which supervisors will complete at various stages of their careers, ensuring a well-trained cadre of supervisors and managers.

The Centers and Offices conduct annual training needs assessments to determine what training is needed in their organizations. Specific curricula have been established to provide the necessary scientific, technical, and regulatory training.

The Center for Biologics Evaluation and Research, for example, has established curricula for reviewers and inspectors. A new Case Study Seminar Series is also being planned. CBER is also in the beginning of establishing a "Staff College" for additional development and delivery of center-specific courses.

The Center for Drug Evaluation and Research is expanding its program of scientific seminars and "Scientific Rounds." CDER is also implementing Team Based Project Management Training for teams involved in reviewing User Fee related drug applications. CDER has a well established "Staff College" with a clearly defined curriculum of scientific and technical courses designed to build and enhance the skills of its employees.

The Office of Regulatory Affairs has included a training component in its internal overall strategic plan. They are establishing "change facilitators" in each district office who will address such issues as implementing Self Directed Work Teams, changing the supervisor/employee ratio and effectuating other NPR initiatives. Also, they continue to provide extensive entry-level training for investigators and laboratory analysts in the Field.

The Center for Devices and Radiological Health has also established a "Staff College" and has begun development of the curriculum to meet the scientific and technical needs of its staff, including courses in Basic Statistics and Biotechnology. They

are also currently developing a training course for medical device application reviewers.

Training is provided through various mechanisms utilizing in-house as well as external expertise. Several Centers are planning for the development of interactive video and computer training technologies as alternatives to traditional classroom training. Management of the training function will also be enhanced through the use of new computer-based systems which will provide for "paperless" administrative processes.

MEDWATCH

Mr. DURBIN. Dr. Kessler, you indicated that the Agency published in the Federal Register a new form for reporting adverse events for drug reactions. The program is called Medwatch. How does the new program work?

Dr. KESSLER. The purpose of the MedWatch program is to enhance the effectiveness of postmarketing surveillance of all medical products, such as drugs, biologics, medical devices and special nutritional products, regulated by the FDA through educating health professionals about the critical role they play in the detection of serious adverse events and important product problems.

As part of MedWatch, FDA has developed several ways to make it easier for health professionals to report directly to the Agency on any medical product. The simplified MedWatch reporting form replaces five other forms previously used for reporting—dependent on type of product and problem. The self-addressed, one-page form, which can be folded and mailed postage-free, is widely available in several publications, including the Physicians' Desk Reference, FDA Medicaid Bulletin, and AMA Drug Evaluations.

In addition, the Agency has established a special 24-hour, 7-days-a-week toll-free telephone line that health professionals can use to obtain information on reporting and copies of the reporting form by mail or fax. Although adverse events drugs cannot be reported over the phone, health professionals are able to report drug quality problems and adverse events or product problems that occur with medical devices.

Health professionals may also fax their reports to FDA via another toll-free number and may submit their reports electronically by computer modem via a third toll-free number.

Voluntary reporting forms are triaged to the appropriate product specific safety surveillance program within FDA. Each report is entered into a data-base and receives a hands-on evaluation by a post-mandatory reports submitted by manufacturers, device distributors, and user-facilities—device reporting only—who have a regulatory requirements to report and who do not report through the voluntary MedWatch program. Based on all of these reports, FDA can take regulatory action ranging from labeling changes, to Safety Alerts, to product withdrawal.

Feedback to health professionals is an important component of MedWatch. The Agency regularly communicates important product safety information product safety information in the FDA-written columns in specific health professional journals. In addition, about 80 health professional organizations have signed on as MedWatch partners. These partners have agreed to promote the MedWatch program and disseminate information to their membership through activities such as publishing newsletters and journal articles.

FAIR PACKAGING AND LABELING ACT

Mr. DURBIN. For the record, please describe your activities related to the Fair Packaging and Labeling Act in 1992 and 1993. Include with that a table showing the number of violations to the Fair Packaging and Labeling Act.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

FAIR PACKAGING AND LABELING

During fiscal years 1992 and 1993, FDA continued to monitor food products for adherence to the requirements of the Fair Packaging and Labeling Act (FPLA) under its Domestic and Import Food Labeling and Economics Compliance Programs. Beginning in fiscal year 93, FPLA activities for seafood products only are covered under the Domestic and Import Seafood Compliance Programs. All other products continue to be covered under the Domestic and Import Food Labeling and Economics Compliance Programs. All of these programs direct coverage of domestic and imported foods for violations under the Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act.

The following have been reported under FPLA activities for fiscal years 1992 and 1993:

INSPECTIONS

Fiscal year	Total	Total adverse	Percent adverse (violations)
1992	57	16	28
1993	66	30	45

DOMESTIC SAMPLES

Fiscal year	Total samples analyzed	Total adverse violations	Total label	Review	Total adverse label reviews violations	Percent
1992	71	51	72	32	18	56
1993	52	31	60	4	4	100

IMPORT SAMPLES

Fiscal year	Total sps analyzed	Total adverse violations	Percent Total label	Review	Total adverse label reviews violations	Percent.
1992	692	542	78	462	389	84
1993	442	370	84	256	239	93

Notes.—Inspections under the FPLA are not conducted separately but rather in conjunction with regularly scheduled domestic food safety inspections.

Total adverse inspections is the total of inspections classified as VAI-3 (if not corrected, violations would warrant additional regulatory follow-up) and OAI (regulatory or administrative sanctions recommended).

For sample analyses, the same sample may be counted under samples analyzed, and label review. An adverse sample classification (lab class 3) indicated that the product failed to meet established standards and guides, are of a level of and/or significance to support a recommendation for regulatory action.

Mr. DURBIN. How is this program funded? What resources did you expend in fiscal years 1990, 1991, 1992, 1993, and 1994?

Dr. KESSLER. I will be happy to provide for the record a table showing the actual and estimated expenditures for 1990–1994.

[The information follows:]

Expenditures for the Fair Packaging and Labeling Act Activities

(Dollars in thousands)

1990 \$516

1991	847
1992	1,043
1993	940
1994 est.	1,084

IMPORT MILK ACT

Mr. DURBIN. In the past, you have indicated that you have spent very few resources related to the Import Milk Act. What resources did you expend on this Act during fiscal year 1993 and what activity do you have ongoing in 1994?

Dr. KESSLER. For fiscal year 1993 approximately 80 hours were expended in reviewing one application for permit to import frozen cream from New Zealand, and answer inquiries related to the Import Milk Act from interested parties in foreign countries.

Application review involves the examination of information provide on standard FDA forms to determine the degree of compliance with requirements of the Act. Per Compliance Policy Guide 7119.05, the Import Milk Act states that "milk or cream may be imported only by the holder of a valid import milk permit. Before such a permit is issued; all cows must be physically examined and found healthy; if the milk or cream is imported raw all cows must pass the tuberculin test; the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; bacterial counts of the milk at the time of importation must not exceed specified limits; and the temperature of the milk or cream at time of importation must not exceed 50 degrees F."

Mr. DURBIN. Do importers pay for any of this activity?

Dr. KESSLER. The permit applicant pay all cost associated with the examination of cows, the inspection of the dairy farm and/or processing plants, and the bacterial assays. FDA does not levy a fee for either granting the permit or processing the application.

HEALTH FRAUD

Mr. DURBIN. Please provide for the record a table showing the resources that FDA committed to health fraud activities during fiscal years 1985 through 1994.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

RESOURCES EXPENDED ON HEALTH FRAUD ACTIVITIES

[Dollars in thousands]

Fiscal year	FTEs	Amount
1985	40	\$1,800
1986	39	2,016
1987	39	2,194
1988	39	2,262
1989	41	2,698
1990	46	3,027
1991	46	4,198
1992	64	4,591
1993	61	4,594
1994 est	61	4,618

MONITORING FOREIGN PRODUCTS

Mr. DURBIN. What relationship do you have with the U.S. Customs Service related to monitoring drugs approved in other countries being brought into this country?

Dr. KESSLER. Section 801 of the Federal Food, Drug, and Cosmetic Act requires that the Customs Service deliver to FDA samples of—inter alia—drug products being imported into the United States. Over the years, cooperative programs between Customs and FDA have resulted in operating procedures by which Customs notifies FDA of the arrival of *all* FDA-regulated imports, and FDA decides which products to sample and collects the sample.

Mr. DURBIN. What about monitoring other FDA regulated items such as food products?

Dr. KESSLER. The approved status of a product in a foreign country has no direct bearing on FDA's decision to admit or refuse the product, although Section 801 directs that products "forbidden or restricted in sale in the country in which it was produced or from which it was exported" shall be refused admission into the United States.

FDA and Customs pilot tested an electronic interface to screen and process FDA-regulated imports in Seattle, Portland, and Blaine, Washington in 1993. A modified version of this interface is being implemented in 18 major ports—which account for approximately 82 percent of FDA-regulated imports—in 1994.

Mr. DURBIN. At one time FDA was considering using U.S. Customs computer operations to help monitor foreign shipments. Have you contributed any funds toward this effort?

Dr. KESSLER. FDA has budgeted \$1,026,000 for its portion of the interface, and has transferred \$264,000 to the Custom Service as compensation for the expenses it has incurred.

OFFICE OF CRIMINAL INVESTIGATIONS

Mr. DURBIN. Just recently, you started training an FDA field force for the Office of Criminal Investigations. What do you anticipate spending on the Office of Criminal Investigations during fiscal year 1994?

Dr. KESSLER. In FY 1994, FDA will spend about \$15 million to support the Office of Criminal Investigations. Of this amount, about \$11 million will be for salary and benefits for the 155 FTEs supporting this activity, \$925,000 will pay rent for the six existing locations they occupy. In addition, the Agency will incur start up expenses of approximately \$565,000 to establish three new sites.

Mr. DURBIN. Where will this staff be located?

Dr. KESSLER. The OCI currently has six field sites in addition to their headquarters office in Rockville, Maryland. These offices are located in Chicago, Illinois; San Diego, California; Kansas City, Kansas; Miami, Florida; Calverton, Maryland; and Jersey City, New Jersey.

OCI will be securing three additional sites including Austin, Texas; San Francisco, California; and San Juan, Puerto Rico. Each of these sites will be staffed with approximately three investigators.

FOREIGN INSPECTION PROGRAM

Mr. DURBIN. For the record, please provide a table showing the resources expended on foreign inspection programs for fiscal years 1992, 1993, and 1994.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

EXPENDITURES FOR FOREIGN INSPECTIONS

The figures listed below include the foreign inspection travel (transportation and per diem costs and the cost of two training courses held to prepare additional FDA employees to conduct foreign inspections.

TRAVEL AND PER DIEM

Fiscal year 1992: \$596,000; Fiscal year 1993: \$1,357,000; and Fiscal year 1994: \$368,500.¹

TRAINING FOR FOREIGN INSPECTION

Fiscal year 1992: 75 investigators, total, \$75,000; Fiscal year 1993: 75 investigators, total, \$75,000.

IMPORT SUPPORT AND INFORMATION SYSTEM PROJECT

Mr. DURBIN. How much did FDA spend in fiscal year 1993 on its Import Support and Information System project?

Dr. KESSLER. During FY 93, FDA funded \$926,700 in contracted development costs associated with ISIS. In addition, \$196,200 was used in support of the ISIS project.

Mr. DURBIN. When do you expect to have the ISIS completely on line and up and running?

Dr. KESSLER. ISIS was renamed Operational and Administrative System for Import Support or OASIS. The Electronic Entry Processing System—EEPS, a subset OASIS, will be implemented at 12 ports by the end of the 4th quarter of FY 94. EEPS will be implemented at six additional ports during the first quarter of FY 95. Implementation of OASIS will continue in FY 96 and be completed in FY 97.

IMPORT SAMPLES

Mr. DURBIN. For the record, how many import samples did FDA take during fiscal year 1993?

Dr. KESSLER. In FY 1993, FDA collected and physically analyzed 27,248 samples. An additional 15,586 samples received label reviews and/or were documentary.

Mr. DURBIN. With better computerized targeting, do you intend to take more samples or fewer samples in 1994?

Dr. KESSLER. The new computerized system will not enable the Agency to collect more samples. It will provide us with better information to more effectively select products of high public health and low compliance history.

Moreover, initiation of the new system may result in fewer sample examinations because some operational personnel will be shift-

¹ October 1, 1993–January 31, 1994 only.

ed from traditional operations to maintenance and control of system activities.

IMPACT OF A HIRING FREEZE

Mr. DURBIN. There is a lot of concern by the industries that you regulate that the Administration's hiring freeze imposed on senior level employees will severely impact your ability to carry out your programs. What impact has the hiring freeze had on the FDA operations?

Dr. KESSLER. In implementing the President's Executive Order to reduce senior level positions, last October agencies were issued a senior level staffing target. The target issued to FDA was 1,288, excluding Commissioned Corps officers. At the time FDA had an on board senior level base of 1,389, excluding Commissioned Corps. We are very concerned with the ceiling since we were preparing to have a net increase in employment of 600 new positions by the end of the year; most of that was focused in areas like drugs, biologic, and device review where our entry level grade for physician reviewers is a the senior level.

In addition the drug, biologic, and device review divisions, about 30 percent of all existing staff meets the definition of "senior level" staff. Even if we had not been trying to add new staff, we could not have lost enough people through attrition to get down to the 1,288 staffing target. We have asked the Assistant Secretary for Health for some relief from the new ceiling target on the theory that, since the senior level reductions were articulated as a percentage of overall reductions, the number should be reconsidered if there are no overall reductions—which is the case for FDA.

Pending a final decision on FDA's senior level target, at the request of the Assistant Secretary for Health, I have been personally approving all promotions and accessions which would add to FDA's number of senior level positions. Although the number of exceptions I have approved has been small, I have approved senior hires critical to the user fee legislation.

Mr. DURBIN. How many senior level people did you have at the beginning of FY 1993 and how many did you have at the beginning of FY 1994? Please break senior level positions down by grade using each individual grade affected by the freeze.

Dr. KESSLER. At the beginning of FY 1993, our senior level staff totaled 1,289, which included 824 GS-14's, 382 GS-15's, and 83 SES's. In early FY 94, senior staff totaled 1,389, which included 901 GS-14's, 411 GS-15's, and 77 SES's.

Mr. DURBIN. It is my understanding that many of the positions hired for the Prescription Drug User Fee Act would normally be senior level grades. How will you comply with the mandates of the Act if you are not able to staff positions at the proper level?

Dr. KESSLER. In accordance with OMB Bulletin 93-08 dated March 4, 1993, senior level reductions apply only to full time permanent employees at grades 14 and above. The Agency has been successful in hiring reviewers for our user fee program areas at pay levels equivalent to GS-14 and 15 through the Staff Fellow/Visiting Scientist program.

Under the authority of the U.S. Public Health Service Act, these time limited appointments are exempt from the Classification Act

of 1923, as amended. Positions filled are ungraded and pay is administratively determined. We have also used non permanent, time limited competitive service appointments to fill grade 14 and 15 reviewer positions. Although we have had success with these alternative hiring authorities, there have been potential candidates who have turned down job offers due to the insecurities associated with time limited appointments. In addition, all of these time limited appointments have restrictions on the total number of years employees can serve on them.

Other possible solutions within the context of achieving government-wide staffing reduction goals are currently being reviewed.

Mr. DURBIN. How many senior level people did you hire in FY 1993 for activities of the Act? If you fill these positions, how will you staff the rest of the Agency?

Dr. KESSLER. In FY 1993, we hired from outside FDA, 6 GS-14's, 2 GS-15's, and 2 SES's to work in PDUFA areas. In addition, we have filled equivalent positions through the Staff Fellow/Visiting Scientist Program and non-permanent, time limited appointments. These accounted for 17 hires in FY 93.

For the rest of the Agency, we will continue to use the Staff Fellowship/Visiting Scientist Program and non-permanent, time limited competitive service appointments.

SELENIUM

Mr. DURBIN. Dr. Kessler, as you know my home State of Illinois is one of the largest pork producing States in the country. There is an issue of great concern to my pork producers related to supplements in animal feed. Selenium is an essential trace mineral for normal growth and reproduction in swine. In many parts of the country, the selenium concentration in forage and grain do not contain sufficient selenium to meet the animal's nutrient requirement. It is my understanding that in September of last year you issued a final rule in the Federal Register that changes to approved level of selenium supplementation in feeds from .3 to .1 parts per million. Evidently you have said that in order to assist the industries involved that you would not enforce this rule for a year. But my question is what happens then?

Dr. KESSLER. We recently participated in an Environmental Roundtable on Selenium sponsored by the Forum for Animal Agriculture in which research needs were discussed. We are committed to examining the progress made on the research required to complete an adequate environmental analysis to determine the continued validity of the stay. If there is adequate progress on the research to collect the environmental information, the stay would be extended. If we determine that there is inadequate progress, the Agency could begin proceedings to revoke the 1987 Amendment in its entirety.

Mr. DURBIN. What should the producers do when these animals get sick?

Dr. KESSLER. We recognize that the level of 0.1 ppm supplemental selenium may not be sufficient to meet the requirements in certain cases. For weanling wine the approved level remains at 0.3 ppm. For other classes of swine the selenium requirement could be met by using feeds that naturally contain higher levels of selenium.

Increasing the vitamin E level of the diet may also be beneficial in reducing occurrences of selenium deficiency.

Mr. DURBIN. I have been informed that you are currently assessing progress on research to further evaluate the environmental impact of selenium in animal feeds. If that is true, on what basis did you approve the change last September? For the record, please provide me a synopsis of the information on which you based your decision. If you are still evaluating the information, does it make sense to impose changes when it is apparent that the review process is not complete?

Dr. KESSLER. The Agency determined that the information submitted to us and in the published literature was inadequate to determine whether or not selenium supplementation of animals results in waste that may cause selenium-related environmental impacts. Research studies are required to satisfy the unanswered questions. Because the environmental portion of the food additive petition was found to be inadequate, the 1987 amendments were stayed. The Agency's evaluation of the available information is consistent with the official opinion of the Department of Interior, and the evaluation completed by the Environmental Protection Agency in response to a request by Congressman Dingell.

FDA CONSOLIDATION

Mr. DURBIN. Two years ago Congress appropriated \$200,000,000 for consolidation of the 40 plus FDA headquarters facilities. We know that you have been in continuous discussions with OMB. Can you tell us the status of the consolidation efforts?

Dr. KESSLER. We will be happy to provide this information for the record.

[The information follows:]

STATUS OF FDA CONSOLIDATION

Because the consolidation plan for FDA headquarters programs, which was approved by the previous Administration and submitted to Congress on July 29, 1992, failed to completely address the major facility related objectives of the FDA Revitalization Act (P.L. 101-635), FDA developed a revised proposal for consolidating its metropolitan area programs. The new FDA plan was presented to GSA on September 30, 1993 and to the Office of Management and Budget (OMB) on December 15, 1993. Additional meetings among the agencies and with OMB continued through early March, and agreement has been reached on a plan totaling \$890 million. Additional funds would be requested in GSA budgets.

The current Administration plan calls for phased construction of new facilities on newly purchased property in both Montgomery County, Maryland and Prince Georges County, Maryland. In the first phase of the project, new laboratory and office facilities will be constructed for FDA's Center for Drug Evaluation and Research. Additionally, new laboratory facilities (Module II) will be constructed for the Center for Veterinary Medicine. In order to guarantee that construction of Module II would not be further delayed, GSA will reprogram \$6,000,000 from another local project to augment the \$274,000,000 already appropriated by Congress. Consolidation of remaining programs would occur in later phases, center by center as additional funding is made available in fiscal years 1996 through 1999. Consolidation is planned to be completed in mid 2003.

NCTR AND FIELD LABORATORIES

Mr. DURBIN. What role will the National Center for Toxicological Research play in supporting field laboratories?

Dr. KESSLER. FDA has a first rate research facility at NCTR. Moreover, it is a facility that is owned and controlled by FDA. Any

plans we develop would address how we can capitalize on our existing facilities and expertise.

BUILDING AND FACILITIES PROJECTS

Mr. DURBIN. For the record, please provide a brief description of each of the projects that was funded under your Buildings and Facilities account during fiscal years 1992, 1993, and your proposal for 1994.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

**Buildings & Facilities Projects
Funded/Planned**

Fiscal Year 1992

Module I, Beltsville, Md. - Incinerator.....	\$750,000
NCTR, Jefferson, AR. Misc. repairs and improvements.....	850,000
CBER, NIH., Bethesda, Md., Bldg. 29B, construction management, Phase II and misc. const. costs.....	480,000
CFSAN, FB-8 - Repair autoclaves and HVAC.....	145,000
CFSAN, Dauphin Is., Ala., Misc repairs and improvement- replace boiler, renov. boil. room and mach. shop.....	460,000
CVM, Beltsville, Md., Incinerator, pad and installation.....	392,000
CBER, NIH, Bldg. 29 - Loading dock, expand and enclose....	376,000
CBER, NIH, Bldgs-29 and 29A- Miscellaneous repairs and improvements - labs.....	268,000
Headquarters, Wash. D.C. Metro Area - Miscellaneous repairs and improvements.....	529,000
ORA, San Francisco and Winchester, Mass., above standard buildouts and misc. repairs and improvements.....	1,650,000
ORA, Various locations, Hazardous waste storage bldgs....	300,000
ORA, Miscellaneous repairs and improvements, Nationwide.....	<u>2,150,000</u>
TOTAL, FDA.....	8,350,000

Fiscal Year 1993

NCTR, Jefferson, AR.- Roof superstructure - Bldg. 14.....	\$460,000
Street lighting system.....	194,000
Underground storage tanks.....	216,000
Asbestos removal - boiler No. 2.....	105,000
Centrifugal chiller conversion.....	180,000
Restrooms and showers renovations.....	240,000
Pavement repairs.....	722,000
Module I, Beltsville, MD - Replace flooring / engineer- ing study (AAALAC).....	529,000
CBER, NIH, Bethesda, MD, - A/E study, Bldgs. 29 and 29A...	100,000
CFSAN, Davisville, RI. - Boiler replacement.....	175,000
Dauphin Is., ALA, - Masonry repair.....	164,000
CVM, Beltsville, MD. - Temporary office buildings.....	270,000
ORA, San Francisco, CA. - New facility buildout.....	1,595,000
San Juan, PR. - Repairs and improvements.....	271,000
Seattle, WA.- Repairs and improvements, casework....	214,000
Misc. repairs and improvements, Nationwide.....	1,265,000
Headquarters, Wash. DC Metro Area - Misc. rep & imp.....	<u>1,650,000</u>
TOTAL, FDA.....	8,350,000

Fiscal Year 1994

NCTR, Jefferson, AR - Replace incoming elec. Bldg.9.....	\$1,322,000
Miscellaneous repairs and improvements.....	186,000
ORA - Kansas City - Decontamination of prior facility.....	750,000
San Juan, PR - Repairs and improvements - Bldg.8.....	250,000
Los Angeles - General facility renovations.....	1,600,000
CBER, NIH, Bethesda, MD. - Retrofit Bldgs. 29 and 29A....	1,300,000
CFSAN, Mod 1, Beltsville, MD. - AAALAC improvements.....	907,000
Dauphin Is., ALA - AAALAC improvements.....	600,000
Davisville, RI - Hazardous waste facility, seawall repair, misc. repairs and improvements....	735,000
Headquarters, Wash. DC Metro Area - Misc. repairs and improvements.....	250,000
ORA - Nationwide - Miscellaneous repairs and improvements..	<u>450,000</u>
TOTAL, FDA.....	8,350,000

BUILDING AND FACILITIES BACKLOG

Mr. DURBIN. Please provide us a list of backlog of Buildings and Facilities projects that are known.

Dr. KESSLER. Mr. Chairman, thanks to your support for these projects last year, our most pressing needs will be worked on. I will be happy to submit a list for the record of the backlog of unfunded projects that FDA will face over the next three years.

[The information follows:]

Buildings and Facilities Project Backlog March 24, 1994

1. CFSAN & CDER; Module 1, Beltsville, MD; Renovations of Labs to suit OSHA requirements, and modifications to permit carcinogen work	\$2,680,000
2. CFSAN & CDER; FB-8, Interim repairs to labs, and replace autoclaves	3,300,000
3. CBER; Bethesda, MD; Buildings 29 and 29A, Renovations of 15 Laboratories	900,000
4. CFSAN; GCTSU, Dauphin Island, AL; Misc Repairs and Improvements	650,000
5. NCTR; Jefferson, AR; Central Boiler Plant repairs	200,000
6. CFSAN; Module I, Beltsville, MD; Installation of Center Lab Benches	350,000
7. NCTR; Jefferson, AR; Upgrade Center Wide Utility Systems	2,033,000
8. CFSAN; BRF, Beltsville, MD; Replacement of Plumbing to Eliminate Lead Contamination	200,000
9. CFSAN; NETSU, Davisville, RI; Construct Haz-Waste Facility, Renovate Micro Lab, Rebuild Seawall, and Miscellaneous R&I	1,750,000
10. ORA; Various Locations, Outfitting of new District Laboratory Facilities-General R&I	50,435,000
11. CDER; Outfitting of new laboratory facility for the National Center for Drug Analysis	3,000,000
12. NCTR; Jefferson, AR. Renov. and Improvements, Bldg. 10. Estab. Library/Conf./Training Center	2,264,000
13. NCTR; Jefferson, AR. Renov. and Improvements, Bldg. 14. Consolidate Chemistry Functions	4,140,000
Total backlog of repairs and improvements	71,902,000

Note.—This project compilation is based upon ORA field labs remaining in current geographic locations.

Mr. Skeen, would you like to follow up?

Mr. SKEEN. Thank you, Mr. Chairman. And you certainly do not lack for focus.

I want to welcome all of you and wish you good morning. It is great to see you back again and I am glad that you brought all of your company with you.

Dr. Henney, I understand that you are leaving FDA and going to New Mexico, the University of New Mexico?

Dr. HENNEY. Yes, sir.

Mr. SKEEN. What position will you have there?

Dr. HENNEY. I will be Vice President for Health Sciences at the University of New Mexico.

Mr. SKEEN. Well, we are certainly glad to have you and welcome you to New Mexico.

Dr. HENNEY. Well, it has been a real privilege to serve this agency and to appear before you. I will miss Federal service very much. As you know, I have come in and out of Federal service now twice. I have enjoyed both stints but I am looking forward to the opportunity at the university.

Mr. SKEEN. Well, I am sure you will miss Washington and the weather.

Dr. HENNEY. That is at the top of the list.

Mr. SKEEN. And the 14th Street Bridge or the Shirley Highway.

Dr. LEE. Mr. Skeen, if I might also add, it is a great loss to the Department. Jane is one of the most highly regarded people in the Public Health Service and in the Department and it is a great loss but it is a great addition for the University of New Mexico.

DIETARY SUPPLEMENTS

Mr. SKEEN. Well, I am sure—you are not losing her because she will be in contact with you, I think. We do not lack for communication in New Mexico.

Anyway, we have talked about tobacco this morning and now, let me ask you something that has been bothering us in our part of the country. We have heard complaints about the alleged Food and Drug Administration raids on dietary supplements with enforcement actions on those people who manufacture them.

As a matter of fact, we have had an operation that has been going on in Nevada and New Mexico that claims that the FDA has raided them without any notification whatever and confiscated over a million dollars worth of vitamins and vitamin supplements, computer equipment, and other things.

Is this a true statement, or is it not? Have you been conducting this kind of raids without any notification?

Dr. KESSLER. Congressman, I have no specific knowledge of the case that you are talking about and I would appreciate you sharing what case you are referring to.

Let me say that back in May of last year there were 35 search warrants executed by Federal and State agents in investigations of several companies and individuals involved in illegal distribution of unapproved prescription drugs. That was an interagency effort coordinated by the U.S. Attorney in the Southern District of California aimed at mail fraud, money laundering, smuggling, drug misbranding, and introducing unapproved and misbranded drugs into interstate commerce.

Those were not simply dietary supplements. Those were drugs with super potent concentrations of active ingredients. For example, Hydergine was found at 311 percent of the labelled potency. Deprenyl was contaminated with methamphetamine.

I am not sure whether you are referring to this action. This action was not targeting dietary supplements. This had to do with prescription drugs that we had very significant concern were coming from mail order services that we believed may be violating the Federal Food, Drug, and Cosmetic Act. That is not dietary supplements. But I would be happy—

Mr. SKEEN. Well, I will share with you the specifics but I would rather not do it in an open—

Dr. KESSLER. Sure. I would be happy—

Mr. SKEEN. Because I want to be fair to both sides of this argument.

Dr. KESSLER. Sure.

Mr. SKEEN. And I would like to hear your side of it.

Dr. KESSLER. Again, I do not know whether this is what you are referring to, but I am aware of this action coordinated by the U.S. Attorney for the Southern District of California. It involved multiple States. But, again, it involved unapproved prescription drugs and illegal distribution.

I do think this case involving the kinds of drugs that I am talking about, with the super potency and sub potency and the very serious health risks, and some drugs without the active ingredient they claimed to contain, and distribution of this stuff without medical supervision; is certainly what the Agency is all about.

But, again, if there is other information about another case, I would be happy to work with you, Congressman.

DIETARY SUPPLEMENTS ENFORCEMENT

Mr. SKEEN. Well, are you required by law to send a notice, an adverse findings letter to food supplement producers or anybody that you feel is not complying with the law?

Do you send them any kind of a warning letter before the action is taken?

Dr. KESSLER. Again, it depends on the kind of violation we are talking about and what provision of the Act.

Mr. SKEEN. Just in food supplements.

Dr. KESSLER. Again, I would need to know the specifics; I apologize. I would just need to know the kind of violation that we would be dealing with. If someone is smuggling in unapproved drug products, there are certain criminal provisions of the Act that kick in and we would follow those.

I mean, if there were civil issues of adulteration and misbranding and quality, that obviously would dictate other procedures. So, again, I just apologize. Without knowing the facts—

Mr. SKEEN. Well, I do not want to blind side you either. How many criminal or civil actions are you taking at the present time in this regard against any violators of any of your regulations?

Do you actually do the enforcement through FDA yourself?

Dr. KESSLER. We have a very skilled set of field investigators in our Office of Regulatory Affairs and throughout this country. We have an Office of General Counsel that reviews those findings. We have an Office of Criminal Investigations. We coordinate our activities. The particular actions that I referred to were the result of an interagency action involving U.S. Customs, the IRS, California Department of Justice, the California Bureau of Narcotics and Enforcement, and the Florida Office of the State Prosecutor.

Mr. SKEEN. You use a lot of enforcement agencies. Do you actually train any law enforcement personnel within the department?

Dr. KESSLER. Yes. As the Chairman mentioned, our Office of Criminal Investigations went on line several weeks before the Pepsi tampering and I was awfully glad that they were around. But we now have this Office of Criminal Investigations staffed by fully trained investigators, as well as our field investigators, who are trained in both relevant law and science.

Additionally, our Office of General Counsel, on criminal matters, would coordinate with and refer issues to the Department of Justice.

Mr. SKEEN. Let us move on. I will meet with you later. I would like to have a meeting with you about this particular case.

Dr. KESSLER. We would certainly be pleased to have that and we would be pleased to receive the facts.

Mr. SKEEN. Well, I need the information and we also need to get a clear idea of just exactly what has been going on. I want to be fair to both sides of this thing.

Dr. KESSLER. I appreciate that.

Mr. SKEEN. We have had the complaint. I want to clear it with you.

Dr. KESSLER. Sure.

BOVINE SOMATOTROPIN (BST)

Let me move on to this bovine somatotropin situation with labeling, BST, that is being used by the dairy industry to enhance the production of milk. I understand that we have some processors of dairy products that are misusing the labeling in this regard. Are you aware of this situation?

Dr. KESSLER. Congressman, we issued guidance on labeling because we were requested to do that by several States. We did that shortly after the time we approved the drug.

The States came to us and asked us to issue guidance on what would be appropriate to put on the food label if the product did or did not use milk from cows injected with recombinant bovine somatotropin—

We issued that guidance but in fact that was only guidance.

Mr. SKEEN. What have you done or have you handed down any judgment on BST?

Dr. KESSLER. Yes, Congressman. Our responsibilities for BST have been twofold. One involved an application that was submitted. Our job was to look at the science of that application and determine whether the product was safe and effective. So we looked at the science. There were multiple advisory committees over a number of years that looked at the science of the product and concluded that the use of the product was safe and effective. So an approval letter was sent.

Secondly, we not only review new animal drugs, but we are also responsible for how those drugs get labeled, and if those drugs are used in food-producing animals, we have jurisdiction over the labeling of the food that is produced from those animals.

So we were asked to issue guidance concerning that labeling, and we did that, so there are two aspects that we were involved in.

Let me just point out that there are a lot of people who have a lot of issues with regard to BST that go beyond this agency's jurisdiction. Our job is to look at the safety of the product both for the animals and for humans, and to look at whether the labeling on a food product is false or misleading.

There are issues being raised—how does this effect the small family farm, what are the economic issues, what are the broader implications for the dairy price supports—which are issues beyond the jurisdiction of the Food and Drug Administration.

Our job is to look at the science and the safety and efficacy and the labeling of product.

Mr. SKEEN. That was the understanding that I had, and I wanted to get it clear, what pronouncement you had made on the drug itself—whether it was safe or not safe.

Dr. KESSLER. Yes, sir.

BST LABELING

Mr. SKEEN. And also the second part of the thing was whether or not some misuse of the labeling has been insinuated by people who are saying that this is BST-free. This insinuate that there was something wrong with the drug.

Would that be a violation of the FDA—

Dr. KESSLER. First of all, the phrase BST-free would be misleading because there's natural BST. What would be more appropriate, if you didn't use rBST, would be to say, from cows not treated with rBST.

Mr. SKEEN. That's natural BST.

Dr. KESSLER. So the BST-free statement would be misleading, but let's deal with the statement, from cows not treated with rBST. That statement, if in fact there were documentation and cows were not treated with rBST, would be a truthful statement.

But there is a section of the Act that says not only does something have to not be false, but it also can't mislead.

Mr. SKEEN. It can't be misleading.

Dr. KESSLER. Correct. So then you get into a very difficult and complex question. Is the statement, not from cows treated with rBST, even though it's a truthful statement, potentially misleading?

Ultimately, to answer that question, we would need to do consumer surveys. What did consumers think? Were consumers in fact misled? Did they think that that milk was better than some other milk? If we took an action, if we wanted to go into court because someone labeled the product like that and we thought that it was in violation of the Act, we would need the results of such surveys.

So we issued guidance and we said the best way—and again, it was very important because there has been some misunderstanding—the best way to assure that the label is not misleading is to put that statement in context. So you give a little more information to make sure that consumers understand that, in fact, there aren't safety issues, or that you are doing it for issues other than safety.

So we suggested the best way to do that was to put it in context, but that was guidance. A lot of people think you cannot label products. In fact, a lot of people think that you can't put the statement, from cows not treated with rBST. That is not correct.

The Agency is permitting, or finding in guidance we've given to our States, who end up enforcing most of the provisions of the milk program, voluntary labeling, which is fine. You can label. Just make sure it's not misleading.

There are a lot of ways to do that, and we're not setting out all the ways, but in fact, voluntary labeling is permitted as long as it is not false or misleading.

USER FEES AND EMPLOYMENT LEVELS

Mr. SKEEN. Thank you for that response, and Mr. Chairman, just one more question. With your budget and the initiation of a pretty healthy amount of user fees involved in this thing, are you hiring more FTEs taking into consideration the increased income from the user fees?

Dr. KESSLER. That's correct.

Mr. SKEEN. Because there is a problem whether your user fees are going to be counted as part of your budget or not.

Dr. KESSLER. Under the Prescription Drug User Fee Act, we have been hiring new medical review officers and new scientists. Under the President's Budget, the medical device user fee program on which we are working with our authorizing committees, would also involve additive user fees, so that it would allow us to enhance our medical device program.

Mr. SKEEN. Thank you for your responses. Thank you, Mr. Chairman.

Mr. DURBIN. Thank you, Mr. Skeen. Mr. Thornton.

ALCOHOL

Mr. THORNTON. Thank you, Mr. Chairman. Dr. Kessler, I'm interested in pursuing the two subjects that our Chairman and Mr. Skeen have discussed, and would like to begin by being specific.

I notice that you have a final rule issued on drug products intended for oral ingestion that contain alcohol. So Dr. Kessler, can you tell me why such a report would be needed?

[Pause.]

Dr. KESSLER. I don't have the rule in front of me, Mr. Thornton, and I am not sure exactly the provision of the regs that you are referring to. Are you talking about the use of alcohol in certain medicines?

Mr. THORNTON. Yes, yes. Well, is alcohol a carcinogenic substance?

Dr. KESSLER. With regard to carcinogenic substances, let me ask—

Mr. THORNTON. I think it would be important to hear for the record.

Dr. KESSLER. Whether alcohol is a carcinogenic substance?

Mr. THORNTON. Yes.

Dr. KESSLER. I'm not prepared to answer that question. I would be happy to submit any evidence we've had on any animal studies—

Mr. THORNTON. Well, is it a medical problem? Is alcohol a medical problem? Why would you be looking at its use as a drug-carrier, if there is no problem associated with it?

Dr. KESSLER. I mean, as a pediatrician, let me tell you what I do have concerns about.

Mr. THORNTON. About fetal alcohol syndrome.

Dr. KESSLER. Absolutely, there's fetal alcohol syndrome, and there is also alcohol that when it is used in certain pediatric medicines, again, the definition of food is food and drink—right?

Mr. THORNTON. Yes.

Dr. KESSLER. The definition of a drug is either intended for the use and treatment, prevention and mitigation of disease, or intended to affect the structure and function of the body.

Dr. LEE. With respect to alcohol, Mr. Thornton, it is a two-edged sword. There is some therapeutic benefits. We've seen some recent publications in the New England Journal of Medicine, for example.

Mr. THORNTON. Yes.

Dr. LEE. With respect to coronary disease.

Mr. THORNTON. As a matter of fact, there are some for marijuana, are there not, in certain circumstances?

Dr. LEE. We are looking at that now.

Mr. THORNTON. Well, it has been in the New England Journal of Medicine.

Dr. LEE. Yes, but we're looking at that. The other is, of course, you have people who become really addicted to alcohol and develop very serious chronic alcoholism.

Mr. THORNTON. Is it an addictive substance?

Dr. LEE. For some individuals, it can be, it is certainly habituating. We talk about addiction medicine. Alcohol, chronic alcoholism, is a serious illness for some individuals.

Now, for others where alcohol is used in moderation, there may be therapeutic benefits. There are dangers for some individuals, and this is particularly true for women during pregnancy, for example—fetal alcohol syndrome, as you mentioned.

On the question of carcinogenesis, we'll ask Dr. Broder at the National Cancer Institute—

Mr. THORNTON. I would like to have that supplied for the record.

Dr. LEE. We certainly will do that.

Mr. THORNTON. Because the medical advice I have is that alcohol is a carcinogenic substance, and I would like to have medical information inserted at this point in the record—

Dr. LEE. We would be glad to provide that for you.

Mr. THORNTON. As to whether that is correct.

[The information follows:]

ALCOHOL ALERT

National Institute on Alcohol Abuse and Alcoholism

No. 21

PH 345

July 1993

Alcohol and Cancer

Cancer kills an estimated 526,000 Americans yearly, second only to heart disease (1). Cancers of the lung, large bowel, and breast are the most common in the United States. Considerable evidence suggests a connection between heavy alcohol consumption and increased risk for cancer, with an estimated 2 to 4 percent of all cancer cases thought to be caused either directly or indirectly by alcohol (2).

A strong association exists between alcohol use and cancers of the esophagus, pharynx, and mouth, whereas a more controversial association links alcohol with liver, breast, and colorectal cancers. Together, these cancers kill more than 125,000 people annually in the United States (1). The following sections discuss alcohol's role in these cancers.

What Is Cancer?

Cancer is a group of diseases characterized by cells that grow out of control; in many cases, they form masses of cells, or tumors, that infiltrate, crowd out, and destroy normal tissue. Although the body strictly regulates normal cells to grow within the confines of tissues, cancer cells reproduce independently, uninhibited by tissue boundaries. Cancer develops in three stages: initiation, promotion, and progression. Cancer-causing agents, known as carcinogens, can contribute to the first two stages.

Cancer initiation occurs when a cell's DNA (the substance that genes are made of) is irreversibly changed so that, once triggered to divide, the cell will reproduce indefinitely. The "change" involves mutations to the cell's genes that can occur spontaneously or can be induced by a carcinogen. In some cancers, it has been shown that the mutations occur in oncogenes, genes that normally promote cell division, or in suppressor genes, genes that normally suppress cell division. Thus, it is believed that cancer-causing mutations result in overpromotion or undersuppression of cell reproduction. During cancer promotion, the initiated cell is stimulated to divide. The stimulus can be natural, as when tissue damage requires proliferation of new cells, or it can be caused by a carcinogen. During cancer progression, tumors produced by the replicating mass of cells metastasize, or spread, from the initial or primary tumor to other parts of the body, forming secondary cancers.

Alcohol's Link to Cancer

Two types of research link alcohol and cancer. Epidemiologic research has shown a dose-dependent association between alcohol consumption and certain types of cancer; as alcohol consumption increases, so does risk of developing certain cancers. More tenuous results have come from research into the mechanism by which alcohol could contribute to cancer development.

Epidemiologic Research

The strongest link between alcohol and cancer involves cancers of the upper digestive tract, including the esophagus, the mouth, the pharynx, and the larynx (3). Less consistent data link alcohol consumption and cancers of the liver, breast, and colon (3).

Upper digestive tract. Chronic heavy drinkers have a higher incidence of esophageal cancer than does the general population. The risk appears to increase as alcohol consumption increases (4-6). An estimated 75 percent of esophageal cancers in the United States are attributable to chronic, excessive alcohol consumption (7).

Alcohol Alert, a publication of the National Institute on Alcohol Abuse and Alcoholism, provides timely information on alcohol research and treatment to health professionals and other interested people. This issue is the twenty-first in the series.

Cancer cells reproduce independently, uninhibited by tissue boundaries

The strongest link between alcohol and cancer involves cancers of the upper digestive tract

A Commentary by NIAAA Director Enoch Gordis, M.D. 3



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • National Institutes of Health

Nearly 50 percent of cancers of the mouth, pharynx, and larynx are associated with heavy drinking (7). People who drink large quantities of alcohol over time have an increased risk of these cancers as compared with abstainers (8,9). If they drink and smoke, the increase in risk is even more dramatic (5,6).

Liver. Prolonged, heavy drinking has been associated in many cases with primary liver cancer. However, it is liver cirrhosis, whether caused by alcohol or another factor, that is thought to induce the cancer (10,11). In areas of Africa and Asia, liver cancer afflicts 50 or more people per 100,000 per year, usually associated with cirrhosis caused by hepatitis viruses. In the United States, liver cancer is relatively uncommon, afflicting approximately 2 people per 100,000, but excessive alcohol consumption is linked to as many as 36 percent of these cases by some investigators (2,12).

The association between alcohol use and liver cancer is difficult to interpret, because liver cirrhosis and hepatitis B and C virus infections often confound data (13). Studies of the interactions between alcohol, hepatitis viruses, and cirrhosis will help clarify these associations with liver cancer (see below).

Breast. Chronic alcohol consumption has been associated with a small (averaging 10 percent) increase in a woman's risk of breast cancer (14-17). According to these studies, the risk appears to increase as the quantity and duration of alcohol consumption increases. Other studies, however, have found no evidence of such a link (18-20).

The inconsistency and weakness of epidemiologic findings suggest that a third confounding factor, such as nutrition, may be responsible for the link between alcohol and breast cancer (15). However, studies that adjusted for dietary factors such as fat intake found that the association between alcohol and breast cancer remained (14,21,22).

Recent studies suggest that alcohol may play an indirect role in the development of breast cancer. These studies indicate that alcohol increases estrogen levels in premenopausal women, which, in turn, may promote breast cancer (23).

Colon. Epidemiologic studies have found a small but consistent dose-dependent association between alcohol consumption and colorectal cancer (15,24), even when controlling for fiber and other dietary factors (15,25,26). Despite the large number of studies, however, causality cannot be determined from the available data.

Other cancers. A few studies have linked chronic heavy drinking with cancers of the stomach, pancreas, and lungs (3). However, the association is consistently weak and the majority of studies have found no association (3).

Mechanisms of Alcohol-Related Cancers

The epidemiologic data provide little insight into whether or how alcohol increases the risk for various cancers. For some cancers, such as mouth and esophageal, alcohol is thought to play a direct causal role. For others, such as liver and breast cancers, alcohol is thought to play an indirect role by enhancing mechanisms that may cause cancer. Studies looking at these direct and indirect mechanisms may shed light on alcohol's role in developing cancers.

Oncogenes. Preliminary studies show that alcohol may affect cancer development at the genetic level by affecting oncogenes at the initiation and promotion stages of cancer. It has been suggested that acetaldehyde, a product of alcohol metabolism, impairs a cell's natural ability to repair its DNA, resulting in a greater likelihood that mutations causing cancer initiation will occur (27). It has recently been suggested that alcohol exposure may result in overexpression of certain oncogenes in human cells and, thereby, trigger cancer promotion (28).

Alcohol as a cocarcinogen. Although there is no evidence that alcohol itself is a carcinogen, alcohol may act as a cocarcinogen by enhancing the carcinogenic effects of other chemicals. For example, studies indicate that alcohol enhances tobacco's ability to stimulate tumor formation in rats (29). In humans, the risk for mouth, tracheal, and esophageal cancer is 35 times greater for people who both smoke and drink than for people who neither smoke nor drink (30), implying a cocarcinogenic interaction between alcohol and tobacco-related carcinogens (29).

Alcohol's cocarcinogenic effect may be explained by its interaction with certain enzymes. Some enzymes that normally help to detoxify substances that enter the body can also increase the toxicity of some carcinogens. One of these enzymes is called cytochrome P-450 (31,32). Dietary alcohol is able to induce cytochrome P-450 in the liver, lungs, esophagus, and intestines (29,33), where alcohol-associated cancers occur. Subsequently, carcinogens such as those from tobacco and diet can become more potent as they, too, pass through the esophagus, lungs, intestines, and liver and encounter the activated enzyme (29,33).

Prolonged, heavy drinking has been associated in many cases with primary liver cancer

Alcohol may affect cancer development at the genetic level

Alcohol may act as a cocarcinogen by enhancing the carcinogenic effects of other chemicals

Nutrition. Chronic alcohol abuse may result in abnormalities in the way the body processes nutrients and may subsequently promote certain types of cancer. Reduced levels of iron, zinc, vitamin E, and some of the B vitamins, common in heavy drinkers, have been experimentally associated with some cancers (29). Also, levels of vitamin A, hypothesized to have anticancer properties (34), are severely depressed in the liver and esophagus of rats during chronic alcohol consumption (35–37).

A recent study indicates that as few as two drinks per day negates any beneficial effects of a "correct" diet on decreasing risk of colon cancer (38). Although the study suggests that a diet high in folic acid, a B vitamin found in fresh fruits and vegetables, decreases the risk for colon cancer, it also warns that alcohol consumption may counter this protective action and increase the risk for colon cancer by reducing folic acid levels.

Mechanisms of liver cancer. The possible role of alcohol in the development of liver cancer is incompletely understood. In Asia and Africa, hepatitis B virus infection is thought to cause most liver cancer; the association is less frequent in the United States. Eighty percent of patients with liver cancer also have cirrhosis (39), and between 27 and 80 percent test positive for hepatitis B or C infection (40). The chronic heavy drinking that causes liver cirrhosis might exacerbate cirrhosis caused independently by the hepatitis B or C viruses. Some studies indicate that alcohol consumption hastens the development of liver cancer in patients with hepatitis C infection (41), whereas others indicate that alcohol has no compounding effect in such patients (42).

Suppression of immune response. Alcoholism has been associated with suppression of the human immune system. Immune suppression makes chronic alcohol abusers more susceptible to various infectious diseases and, theoretically, to cancer (43).

Summary

Although epidemiologic studies have found a clear association between alcohol consumption and development of certain types of cancer, study findings are often inconsistent and may vary by country and by type of cancer. The key to understanding the association lies in research designed to decipher how alcohol may promote cancer. Such studies examine alcohol's metabolic effects at the cellular and genetic levels. Research examining the ways in which alcohol may induce cancers has found some potential mechanisms, the most promising of which implicates oncogenes.

Alcohol and Cancer—A Commentary by NIAAA Director Enoch Gordis, M.D.

As can be seen from this *Alcohol Alert*, the evidence for alcohol's role in promoting some cancers (e.g., cancers of the mouth and throat) is stronger than the evidence linking alcohol use to other cancers, such as breast cancer. Public health policy should reflect the strength of the evidence of alcohol's role in promoting various cancers. Convincing evidence of alcohol's effects on common cancers—even when these effects are minor—has important public health implications. However, it is equally important that the public not be subjected to undue alarm when evidence for an increased risk for cancer due to alcohol use is weak or inconclusive.

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LABELING

Mr. THORNTON. I'm relating this to tobacco, which the Chairman pursued with some vigor, and which I share the Chairman's concerns about because I think it is a great health hazard, and I'm putting it in juxtaposition with, however, an orange juice concentrate which carries Vitamin C. Should we label the orange juice concentrate, and not label alcohol?

Dr. KESSLER. Let me just understand the juxtaposition you are trying to make between nicotine and alcohol.

Mr. THORNTON. No, I'm trying to make the juxtaposition between alcohol and orange juice, right now, or vitamins, or supplements.

Dr. KESSLER. As I understand—

Mr. THORNTON. I'm trying to understand why—

Dr. KESSLER. As I understand it—

Mr. THORNTON. Why you would be inquiring about food supplements and vitamins and concentrated juices—papaya juice and things like that—but I've not seen any labeling on alcohol? I'm wondering—

Dr. KESSLER. Congressman, we can go take a look, but as I understand it, when you look at an alcohol label, you know exactly how much alcohol is in there, and how much you're consuming.

Mr. THORNTON. Do you know what it does?

Dr. KESSLER. If I can just finish, Congressman.

Mr. THORNTON. Please.

Dr. KESSLER. As I understand it—

Mr. THORNTON. I do want a full response.

Dr. KESSLER. If you look at an alcohol label, the proof—two times percentage—will give you the amount of alcohol so you know how much alcohol you are taking.

That is not the same for cigarettes.

Mr. THORNTON. Oh, I have no difficulty in that expression of the contrast between alcohol and cigarettes. I'm more interested in the vigor with which you are proceeding against food supplements which may be a priority, but I'm just wondering if it is of an equal priority to some reflection on the medical problems associated with alcohol use?

Dr. KESSLER. With regard to dietary supplements, the Congress specifically asked us to issue regulations under the Nutrition Labeling and Education Act of 1990, and we've done that.

We spent a very small percentage of our resources; in response to Congressman Skeen. We took action against unapproved drugs. In those cases, I think those do pose a significant public health risk, so we do put our energies behind those substances that pose the greatest public health risk.

PESTICIDES

Mr. THORNTON. Moving from the alcohol and the fetal alcohol syndrome to studies of the effects of certain chemicals, pesticides, and other additives in the diet of pregnant women, both the National Academy of Sciences and the GAO have done reports within the past year saying that there are great deficiencies in government's understanding of the effect of pesticides on pregnant women

and children. This is an area that is in your jurisdiction, and in that of the EPA and the Department of Agriculture.

A year ago I asked what you all were doing to work together to develop some kind of program of cooperation to study this question as to the foods and drugs and their effect on human health and nutrition. Please give me a report.

Dr. KESSLER. Congressman Thornton, you are correct, it is a very high priority for the Administration.

Mr. THORNTON. Do you have agreements with the EPA, or are you pursuing them?

Dr. KESSLER. Yes. In fact, we testified jointly with the USDA and EPA, and we are in the process of completing the actual details of an administration proposal. Those should be available shortly, and I can assure you that the cooperation that you've asked us for will be there.

FACILITIES

Mr. THORNTON. Very good, very good. I appreciate that. You can tell I'm a little bit miffed, and let me tell you why.

Yesterday we inquired what progress had been made towards developing an architectural and design work plan for the relocation, combining of FDA facilities into appropriate locations, and apparently we knew that you were working on a master plan. Yesterday we called to see if we could find out what that master plan was, and we were told that it didn't exist, and that you didn't have it yet.

And I was a little bit concerned to read about it in the Washington Post this morning. Did I call the wrong person? What happened?

Dr. KESSLER. We certainly regret any misunderstandings we may have had.

There are two major activities underway at the Agency in the planning and analysis area.

Mr. THORNTON. Okay.

Dr. KESSLER. And both have to do with program and facilities, but they need to be separated out.

Mr. THORNTON. Okay.

Dr. KESSLER. There is a headquarters issue which deals with the greater metropolitan area where our centers that are located—

Mr. THORNTON. By the way, I applaud the plan that I read about in the Post. I thought it was real good. [Laughter.]

Dr. KESSLER. Thank you, Congressman.

Mr. THORNTON. I liked it, and that does have to do with the metropolitan.

Dr. KESSLER. Yes.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH (NCTR)

Mr. THORNTON. Oh, I'm not a reporter. I applaud it, but now tell me about the other plan because that's what I guess I was really wanting to hear.

Dr. KESSLER. Right. What you read about this morning had to do with the headquarters.

Mr. THORNTON. Yes, sir.

Dr. KESSLER. The consolidation. What your call had to do with was specifically with NCTR.

Mr. THORNTON. It did have to do with that, yes.

Dr. KESSLER. And with regard to our field.

Mr. THORNTON. Yes, sir.

Dr. KESSLER. Now, we have 21 district offices throughout this nation. We have over 100 resident posts. We have laboratories.

Mr. THORNTON. Okay.

Dr. KESSLER. I mean in a number of those districts, and we also have the very fine facility at NCTR.

Mr. THORNTON. Yes, sir.

Dr. KESSLER. And we want to make the best use. We have a wonderful, very highly competent new center director for NCTR.

Mr. THORNTON. Is he here? I'd like to have him introduced. I've heard great things about him.

Dr. KESSLER. Dr. Schwetz, why don't you join us at the table.

Mr. THORNTON. I've heard great things about you.

Dr. KESSLER. NCTR is a very strong, important part of the agency, and one thing, Congressman, you and I have talked about over the last couple of years, and something very important to me, and I know important to you, is to integrate NCTR into the workings of the agency so it can be a vital part.

Mr. THORNTON. Absolutely.

Dr. KESSLER. So it is not just a separate facility. What we're trying to do is to take a look, and I know the Chairman also has been looking, and his staff has been looking at the question of field facilities. We are trying to do an analysis and look toward the future.

With resources being very scarce, how can we make the best use of all of our field facilities including NCTR? That's what we're trying to do. It's not that there has not been any thought. There has been a lot of thought, but these are complex decisions.

Mr. THORNTON. Okay.

Dr. KESSLER. They require a lot of peoples' input before the Administration—

Mr. THORNTON. But you are working on it.

Dr. KESSLER. Absolutely, Congressman.

Dr. LEE. But there is not yet a master plan.

Mr. THORNTON. But there is not yet a master plan.

Dr. LEE. We are working very closely with the FDA. We're looking at the technology. We're looking at the personnel. We're looking at how to, as Dr. Kessler says, do the best job with the resources available, and the modern technology with respect to the laboratory facilities in the field.

When we have that developed, we certainly will provide that information fully.

Mr. THORNTON. Well, I want to thank you, and there is a distinction between the two type plans. I can understand the confusion. I was a little bit concerned when I read the paper, but I assumed that there was a good explanation for it, and you've given one.

I just want to urge you, Dr. Kessler, that you move forward with the kind of steady progress that you often make and are well-known for in developing the same kind of good program for those operations of your agency that are located outside the Beltway, and

by your shaking your head, I believe you are saying that that is your intention to do so.

Mr. THORNTON. Thank you. Mr. Chairman.

Dr. LEE. Mr. Chairman, could I ask to be excused? I have to testify before the Senate Appropriations Committee on the full Public Health Service budget, and if it's agreeable, I would like to be excused.

Mr. PETERSON. Absolutely. Before you go——

Dr. LEE. Yes.

Mr. PETERSON. The Chairman made some statements having to do with allegations, and I would caution you and Dr. Kessler that this town often has investigations that are tantamount to conviction or to a finding.

I think it is important that we reserve the association to guilt as to tobacco and the companies and what things are happening there before the investigation is complete.

Dr. LEE. We certainly agree with that.

Mr. PETERSON. That I think is something that we have to watch very, very closely.

Dr. LEE. Yes.

Mr. PETERSON. This town doesn't do very well at reserving guilt and in your position, I think you need to make sure that that is spoken to as frequently as you can.

Dr. LEE. Mr. Chairman, I'm glad you made that point.

Mr. PETERSON. Mr. Thornton.

Mr. THORNTON. Only after your—I would like to be recognized for one brief additional question.

Mr. PETERSON. The Chair recognizes you.

Mr. THORNTON. Did you want to continue to respond to that?

Dr. LEE. No, I just think that that is a very appropriate comment, and we will certainly, I certainly agree with it, and we would certainly respect that with respect to this investigation.

It is an investigation. It is not, by any means, a decision.

Mr. PETERSON. And I appreciate that, and I just wanted to clarify that because we can take this to a conclusion before the facts would demonstrate the justification for that.

Dr. LEE. Absolutely.

NCTR—ANALYTICAL METHODS

Mr. THORNTON. Mr. Chairman, I just wanted to mention one other thing because Dr. Bernard Schwetz is here, and the NCTR work is extraordinarily good. You say that in your brochure, that it's analytical methods development in conjunction with other centers can develop sensitive techniques to measure adulterants to the food supply including microbial contaminants and disinfectants, and in your testimony, you say that microbial infestations of food are one of the major concerns.

I am delighted to know that NCTR has that capability. That is, Dr. Swetz, I believe, one of the capabilities that a laboratory can handle, is that correct?

Dr. SCHWETZ. Yes, it certainly is. Both the chemical analytical techniques, as well as the microbiological are areas that we have important developmental capabilities at NCTR, and we have worked very closely with the field operations to be sure that we

know what their needs are, and that we can provide them with the best analytical methods that can be developed.

Mr. THORNTON. Thank you very much. Thank you, Dr. Kessler.

Mr. PETERSON. Well, Mr. Thornton, you have taken enough time for Mr. Walsh to leave, so you are left with me now. [Laughter.]

Mr. PETERSON. If I may continue, and I will vote after you all get back.

Mr. THORNTON. After we get back.

Mr. PETERSON. If I may ask actually some budget questions.

Dr. KESSLER. Sure.

Mr. PETERSON. Kind of surprised, right? [Laughter.]

USER FEES

Mr. PETERSON. I'm concerned about the user fee. Unless my math is wrong, in your statement, you're talking about \$324 million is it, in user fees?

Dr. KESSLER. It's \$343.

Mr. PETERSON. Okay, \$343 million. Some of those of course haven't even been authorized yet—as in the case of the medical devices.

Dr. KESSLER. Absolutely.

Mr. PETERSON. And so that's kind of a hope that that might be included, but I am concerned that there is a deficit if you do all of your other math here, of nearly \$228 million.

Where are the rest of the user fees? There is \$79 million for prescription drug which we know about, and I guess we've got the mammography quality standards fee, where is the rest of this?

Dr. KESSLER. Mr. Chairman, the President has had some hard decisions to make in the formulation of his budget, and the Administration has made a serious effort to submit a budget that meets the deficit reduction targets on which the Administration and the Congress have agreed. That's obviously not a very easy task, and it clearly demands that we look at many ideas that may have been cast aside at previous times.

The Administration's budget asks that the Congress consider afresh substantial new user fees to be placed on the industries that FDA regulates.

Mr. PETERSON. Well, I know, but maybe you can enumerate the ones that you have authorized——

Dr. KESSLER. Yes.

Mr. PETERSON. And are in concrete, the ones that you can really count.

Dr. KESSLER. The Prescription Drug User Fee Act that allows us to deal with new drug products and biotech products.

Mr. PETERSON. And that's \$79 million.

Dr. KESSLER. That's correct. Sir, we also have, last year the authorization to collect user fees under the Mammography Quality Standards Act, about \$6 million.

Mr. PETERSON. It's 6.5.

Dr. KESSLER. In the 1995 budget request.

Mr. PETERSON. And therefore, the rest of it, you are betting on future authorization for user fees.

Dr. KESSLER. We are struggling with this issue. It is very complex. It raises many complex issues associated with collecting substantial new user fees.

Mr. PETERSON. Okay, so these are just hopes. Let me ask then, of the user fees that we have already been authorized, and we obviously have supported, has it made the difference? Have you brought down the time lines for the submissions to get through the process? Has that been a success?

Dr. KESSLER. We have made a good start considering that the prescription drug user fee program is a five-year program. It's just begun. The ultimate answer to your question, we will really know in a number of years.

Mr. PETERSON. Yes.

Dr. KESSLER. But we do have some interim goals that we set. We have recruited about 180 additional FTEs on-board to review human drugs. We expect that number to increase to about 350.

The backlogs—our interim goals before, I mean the final years, really reduced the backlogs of drug applications. We've done that in the new drug area. We're down from 35 to 6, and our biologics from 9 to 3, so we are in fact well on our way to meeting the goals.

It's a very important program. It is something from which the pharmaceutical industry, the FDA, and most important, the American public, stand to gain. The pharmaceutical industry is supplying the resources. We are keeping our standards high.

It allows, a reviewer to focus on fewer applications, so if there are important products that can be made available to the American public, they will be made available in as short a period of time as possible, still keeping the high standards of safety and efficacy that we all expect.

MEDICAL DEVICE USER FEES

Mr. PETERSON. You know, in fairness, you are going to the medical devices folks and you are suggesting the successes that you heard on the prescription drugs to sell essentially the support for that, and then at the same time, you really are saying that it will be several years before we really know.

Dr. KESSLER. I think we have to look at what the project entails. After appropriation, we have to hire the medical review officers.

Mr. PETERSON. Right.

Dr. KESSLER. These are highly-skilled, highly-trained individuals. We have existing backlogs. We've committed to some very, very aggressive performance goals, but you are bringing on highly-skilled people. You're training them. You want to reduce a backlog.

We are working with the medical device industry, I mean, in talking to them, in talking to your colleagues on the authorizing committees. I feel very strongly that a medical device user fee program would have enormous advantages for everyone—the medical device industry, for us, and the public. This program would raise revenues to be used for medical device review, to hire medical device reviewing officials, scientists, engineers, and physicians, paid for by the medical device industry. It would allow us to reduce backlogs without lowering standards.

Mr. PETERSON. Well, I tend to think that it is a little optimistic to use the numbers you are using there, and that's the only point I'm trying to make, that those numbers may not materialize.

I will turn this back to the Chairman, and go vote and I will come back and ask additional questions, if I may.

BST

Mr. DURBIN. Dr. Kessler, can I follow up on a couple of things?

First, on the BST question, the folks who are arguing that it is a naturally-occurring hormone, and therefore is not dangerous in and of itself. Others are saying that may be the case, but they are arguing that the use of the drug increases the frequency of infections in cows, leading to more antibiotics being used, which is also a concern in our nation's milk supply.

Do you have any evidence or indication that the use of this drug leads to more antibiotic use in cows?

Dr. KESSLER. Let me just start off with the bottom line, to that question. If there are antibiotics or residues even in any small amounts that end up in milk, there is a very extensive surveillance program which we have put into place over the last several years which requires that such milk be thrown out and discarded.

Mr. DURBIN. That never reaches the market.

Dr. KESSLER. That never reaches the market, so even theoretically if you use more antibiotics with regard to an animal, there are withdrawal times that you have to follow. There are a lot of different safeguards, but there is the ultimate safeguard that virtually all milk is tested, and if there are minute quantities, the milk is discarded.

So I think that is the most important point that people have to understand.

DIETARY SUPPLEMENTS

Mr. DURBIN. Right. Let me also return to a topic that you mentioned in conversation with my colleague, Mr. Skeen, about nutrition supplements.

The nutrition supplement industry engaged what I consider nothing short of scare tactics, advising consumers that the Food and Drug Administration was going to force them to get a prescription for their common everyday vitamins.

There are many Americans who believe in their heart and soul that these vitamins and nutrition supplements are very important to their personal health. As a result, they were frightened by that suggestion and wrote in great volume to their Members of Congress. They suggested that the FDA was going to, in some heavy-handed way, change the way that business is being done in health food stores across America.

Now, we've had a hearing on that at which you have participated.

Dr. KESSLER. Right.

Mr. DURBIN. I will tell you that I believe there are many conscientious and honest people in this industry who are trying to sell a good product to let the consumer decide if it is of value to him or her.

I also believe there are a lot of charlatans and people who are selling things suggesting on the labels and on accompanying brochures that these products do things far beyond anything that can be proven scientifically.

Some of the things we've seen border on the ridiculous. I love this one—Nature's Plus Fuel for Thought. [Laughter.]

I ought to be taking a double dose. The Exercise Edge—it goes on and on, and we had, at the time of the hearing, this desk was covered with them. Including one of the most outrageous which suggested in the brochure that the substance in that bottle would kill the AIDS virus in vitro.

The average consumer reading that says maybe I ought to take a shot of this one just to be careful. You and I know that Diet Pepsi would kill the AIDS virus in vitro. Maybe air would kill the AIDS virus in vitro.

But that kind of misleading advertising has been behind the FDA's efforts to try to police this industry. Now, you've come out with some new labeling requirements as required by Congress.

Tell me what has happened—what kind of changes we've seen in the industry? Were the scare tactics of this vitamin supplement and nutrition supplement industry warranted?

Dr. KESSLER. Mr. Chairman, I think when the word got out, in part because of the hearing that you held last year, that in fact we were not going to make dietary supplements prescription drugs, we were not going to restrict access to high potency vitamins, we weren't going to take anyone's vitamins or minerals away, all we wanted to do in and all the regulations wanted to do was to clean up the labels, for example, of the products that you mentioned.

When people started understanding that, rather than the other claims that were just not true, they realize that they could not be opposed to making sure that labels are accurate. Who is in favor of claims like those for products that are unsubstantiated? For 75 years of this agency's history we have tried to make sure that what's on the label is in fact true.

You know, it's the oldest trick in the book—take 40 cents of ingredients, put a label on the product, and you could sell it for a lot more.

Mr. DURBIN. So when it is all said and done, I guess the real bottom line question is whether the person who wants to take Vitamin C, Vitamin A, whatever it happens to be—garlic—they are still going to be able to buy that over-the-counter. They do not have to go to their doctor for a prescription. The FDA is not trying to expand its jurisdiction in this area. Is that correct?

Dr. KESSLER. We are not looking to take anyone's vitamins or minerals away, that's correct.

DIETARY SUPPLEMENT LABELING

Mr. DURBIN. If I may follow quickly with a few questions. As you know we, Members of Congress, were deluged last year from proponents of the nutrition supplement industry. You issued rules related to labeling recently. Please provide us with a summary.

Dr. KESSLER. I will be happy to provide this information for the record.

[The information follows:]

LABELING OF DIETARY SUPPLEMENTS

In response to the Dietary Supplements Act of 1992, on January 4, 1994 FDA issued a number of documents relating to the labeling of dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances, including: Mandatory Nutrition Labeling, Final Rule; Nutrient Content Claims, Final Rule; General Requirements for Health Claims, Final Rule; Reference Daily Intakes (RDIs), Proposed Rule; and Folate and Neural Tube Defects, Notice.

Nutrition labeling, similar to the nutrition labeling required on foods in conventional food, but modified to be more flexible for dietary supplements, will be required by July 1, 1995. Nutrient content claims (e.g., excellent source of calcium, more vitamin C than a glass of orange juice, etc.), consistent with those allowed on conventional foods, will be permitted on dietary supplements. Health claims on dietary supplements must be supported by the totality of publicly available scientific evidence and the standard used to judge the validity will be the same, whether the claim is on a conventional food or a dietary supplement.

FDA has proposed to establish RDIs for seven additional nutrients so that they may be listed on nutrition labeling. Also, the Agency will permit claims about the role of folate in reducing the risk of neural tube defects to appear on the labels of supplements and folate rich conventional foods.

Mr. DURBIN. Have you taken any enforcement actions related to supplements since final rules were published?

Dr. KESSLER. The Food and Drug Administration has not recommended any regulatory actions, such as seizures, injunctions, or prosecutions related to dietary supplements since the final rules were published January 4, 1994.

Mr. DURBIN. For the record, please tell us what resources were used for nutrition supplement work in FY 93. What do you expect to use in FY 94?

Dr. KESSLER. We do not have specific usage data readily available for FY 1993 because no unique tracking code existed in years prior to FY 1994 for nutrition/dietary supplement work. We estimate that usage was about 121 FTEs in FY 1993 and will be about 121 FTEs in FY 1994. In terms of dollars, our estimated expenditure for FY 1993 was about \$10.2 million and for FY 1994 we estimate about \$10.8 million will be expended.

These resource estimates are based primarily on a very labor-intensive manual review of the FY 1992 field work data files performed as part of a General Accounting Office study in 1993. The FY 1992 figure is based on a broad definition of dietary supplement work including all related activities in the foods and human drugs programs, and also includes resources expended on major criminal cases involving a combination of illegal drugs and dietary supplement products when no breakout between the two product groups could be done. The manual review included more than 80,000 FY 1992 computer records in determining what resources were expended on supplements work by field components in that year. This field data was combined with figures provided by Headquarters elements to arrive at a total estimated usage figure for FY 1992 of 121 FTEs. At this time, our best estimate is that work in this area continued at about the same rate in FY 1993, and will be performed at a similar level in FY 1994.

Mr. DURBIN. I'm going to defer now—I've a few more questions but I will yield because Mr. Pastor hasn't had a chance to ask questions. Mr. Pastor.

Mr. PASTOR. Well, I had a chance during the vote to get my Provigral supplements. [Laughter.]

Mr. DURBIN. There are some more down here.

Mr. PASTOR. Good morning.

Dr. KESSLER. Morning.

USER FEE STUDY

Mr. PASTOR. The Prescription Drug User Fee Act of 1992 required that FDA and its Center for Veterinary Medicine undertake a study of the animal health industry to help Congress evaluate the impact of additive user fees on the drug approval process.

What is your time line for releasing to Congress the report mandated by this act?

Dr. KESSLER. It's a very important activity. We are working hard on it. We are a little behind schedule, in part because of the complexities that the issue raises.

What we have had to do is to assess the current animal drug review process. We've had to look at whether there are problems in the review process with regard to timely review of animal drug product applications and develop goals and objectives to improve that review process, and ultimately to determine the feasibility of charging fees to the animal drug industry to pay for the improvements.

We are doing that as the Congress asked us. You asked us to do that in consultation with the animal drug industry. We have placed a high priority on this study, and I hope that we will have the final product to you very soon.

Mr. PASTOR. How do you define soon?

Dr. KESSLER. Congressman, it is in clearance now. There are multiple parts to that clearance, and we are working very hard on it. Some of those clearance steps are at levels that are higher than I am on a report to Congress, and I just can tell you that everyone is working on it very hard.

Mr. PASTOR. With everybody working on it very hard, is 30 days, six months—just give me a ballpark figure. I'm not going to let you go until you give it to me. [Laughter.]

Dr. KESSLER. We have a little more work to do on it. I'm getting pinned down, right?

Mr. PASTOR. Yes.

Dr. KESSLER. I'm getting pinned down.

Mr. PASTOR. That's a WWF pin-down.

Dr. KESSLER. Let me assure you that we will strive to have it clear the agency within 30 days, if not sooner.

USER FEES—ACCOUNTABILITY

Mr. PASTOR. Okay. My next question deals as you go towards more user fees, I think there's a concern in the community that funds raised through user fees may not be used to help the process or that you will be able to accelerate the approval of new drugs. And, there is a fear that you may use the user fees for other purposes.

What assurances can you give me and the subcommittee that as you increase user fees, that they will be used for the intended purpose. In addition, What process or review is the FDA undertaking to improve its ability to meet future demands? How we are going to use these user fees to make sure that the drugs that we're testing, and other products that we're testing, will be tested quicker?

Dr. KESSLER. All the money that is raised under the Prescription Drug User Fee Act is plowed back into the review of new drugs and biologics, and there are tracking mechanisms and audit mechanisms to assure that.

Mr. PASTOR. So you are mandated by the law to any user fees received—

Dr. KESSLER. Under the Prescription Drug User Fee Act, as it is written, it is very specific that those monies are to be used only for additive personnel and systems to allow speedy review of important new drugs.

Mr. PASTOR. Do you see any new products out in the future that you will suggest that they should have user fees? Packaged foods? Etc.?

Dr. KESSLER. That is exactly what is under review now at the Agency. The President's budget has a request beyond prescription drugs. We talked about medical device user fees.

Mr. PASTOR. Uh-huh.

Dr. KESSLER. And that is very important. Those would be additive user fees to speed the review of important new medical device products. We also have fees for the inspection of mammography facilities. But there is also the proposal to collect \$228 million in user fees from other industries on other types of products, and we are in the process of analyzing this very complex issue.

Mr. PASTOR. What are some of the products that you're analyzing?

Dr. KESSLER. Well, let me give you the jurisdiction, because it really is the jurisdiction of the Agency that we look at. We have user fees in place for new prescription human drugs and biologics.

Mr. PASTOR. Biologics.

Dr. KESSLER. We are proposing additive medical device user fees, and mammography user fees for the inspection of those facilities. In addition, there are foods, there are over-the-counter drugs, there are generic drugs, there are blood products, and you just mentioned animal drug products.

So there are a lot of other regulated products that could certainly be part of the analysis.

DRUG TRIAL DIVERSITY

Mr. PASTOR. There have been some concern in the past that in some of the trial groups, your drug trial groups, that they have been limited.

What is the FDA doing to ensure that when we look at drug trials, we look at ethnic groups, age, and other characteristics that you find in our community?

Dr. KESSLER. In my opening statement, I talked about the commitment of the agency to women's health. Last year we issued guidelines for the inclusion of women, and specifically to address the point that you raise, the elderly, and minorities.

And one issue that is of just recurring concern to me is pediatric study of drugs in children. We don't do enough of it. There is just not enough incentive for it, and very often I am left, and my pediatric colleagues are left without information to take care of a child because no one undertakes those.

But we have made major strides this last year on mandating that women be included in the trials, and also as part of the analysis. We will not file an application unless there is sufficient data there to conclude that it can be safe for all people for which the drug is intended.

Mr. PASTOR. But what efforts are you making to include minorities in these analyses?

Ms. SCHEMAN. There's an enormous amount of outreach going on into different minority groups including Native Americans and Hispanic groups. We work closely, through our Office of Consumer Affairs, with these groups to include them both on advisory committees and also in talking about issues such as clinical trial enrollment.

There is an evolving science about what differences there might be in different ethnic minorities in terms of drug metabolism, but at this point, we're working very hard to ensure that ethnic minorities are in fact represented broadly in all of the activities of the agency.

Dr. KESSLER. Furthermore, Congressman, when we expand our analysis with regard to women, we are also—and it is very important—focusing on the diversity of all women in our review.

FOOD SAFETY

Mr. PASTOR. My next question deals with food safety. In the second page of your testimony, you talk about food safety initiatives that you're undertaking. Could you describe the process you have made in detecting and qualifying microbial pathogens as well as manmade chemical pesticides or natural toxins in foods?

Dr. KESSLER. We have made major advances. There are certainly new bacteria that are emerging, and we need to diagnose rapidly the presence of those bacteria. Some people don't understand that we also have a very strong research program in our center for foods.

If we want to know whether a food is contaminated we may need to run a test. The food is there on the dock and you need an answer very quickly, so you don't have a lot of time to waste. So our scientists have pioneered and developed new diagnostic tools, new DNA probes that would allow rapid screening for contaminants and microbial contaminants.

There is a lot of work going on in that area.

Mr. PASTOR. The Secretary of Agriculture in his testimony said that one of the research agencies of agriculture, I think it's ARS, is working on this problem and they are close to identifying contaminants within—thirty minutes.

They say they are able to detect high levels of a bacteria, but they cannot identify the type of organism quickly. I am interested in seeing not only that the test is done quickly, but that you also are able to identify the particular organism. How far are we in that process?

Dr. KESSLER. We are understanding more about molecular biology and the advances of biotechnology are allowing us to understand more about the characteristics of living cells and bacteria. That technology really has opened up a whole new way of identify-

ing pathogens so we can actually look for certain DNA in these DNA probes.

It is nothing short of revolutionary. We are not there fully. There are still enormous challenges that food safety pose. There are, the emergence of new bacteria, new strains, the evolution that you would expect for pathogens that can survive, continue to present enormous challenges.

You are correct, Secretary Espy I think has taken really enormous strides, I mean, within Agriculture for the products that he regulates to try to develop newer and safer techniques.

I don't want to hold out that a magic bullet is around the corner. Again, adherence to certain rules that have been around for a long time still is very important. Careful processing, careful hygiene, careful sanitation in the processing plant, cooking at home, hand-washing, not cross-contaminating raw and cooked, you know, those things that you hear from us. I can talk about DNA probes and the exciting new kind of research, but there are also some very basic things that we can do everyday.

BORDER INSPECTIONS

Mr. PASTOR. Mr. Chairman, my last question deals with border inspections. As you know, it is a concern which was raised throughout the whole NAFTA debate, that we may be importing products in the United States that are of lesser quality or actually contaminated.

What are your efforts along the U.S./Mexican border to ensure that the high standards are still maintained?

Dr. KESSLER. Let me ask Ron Chesemore, who directs our field force which is responsible for activities at the border to comment, if that's okay.

Mr. PASTOR. Yes, okay.

Mr. CHESEMORE. Mr. Pastor, our efforts are really three-pronged. Not only are we responsible for looking at the product, but I think we have to go way beyond that, and we have to make sure that we spend our efforts wisely, looking at as many of those commodities that come across the border as our resources allow.

Secondly, we work very closely with the U.S. Customs Service, and we have, with the help of this committee this year, added some additional resources along the Mexican border. We have two districts that are really primarily involved there, both the Los Angeles district and our Dallas district.

We concentrate very heavily on the produce that is grown in other countries, and we have a separate import program for Mexican produce.

Thirdly, we also are working closely with the Mexicans, and we are meeting with them regularly, as we are with other countries, to try to improve program operations.

We have made every effort to make sure that we are not sacrificing safety at all through any of our agreements.

Mr. PASTOR. Thank you, Mr. Commissioner. I yield back my time.

Mr. DURBIN. Thanks. Mr. Walsh.

Mr. WALSH. Thank you, Mr. Chairman, and thank you, Dr. Kessler and your staff for this presentation. I just finished reading

an article that was written in October of 1993 in Business Week that said you are doing some good things, and I think it's important that that be recognized.

We tend to focus on the problems, and I think that that's our responsibility, certainly, but I think we should recognize the successes that you've had.

Dr. KESSLER. Thanks.

USER FEE STUDY

Mr. WALSH. You're welcome. I understand Congressman Pastor asked a couple of questions that I was interested in. If you could again comment on this study by the Center for Veterinarian Medicine, that is due to come out soon?

Dr. KESSLER. I've made a commitment here that it will clear the Agency within the next 30 days, but there are clearance steps beyond that. It's a very important complex issue and we're working with the animal drug industry. We are a little behind schedule.

Do you want to comment?

Ms. VEVERKA. Well, in fact, the report is complete.

Mr. WALSH. Fine.

Ms. VEVERKA. So it is just going through the clearance process.

Dr. KESSLER. Within the Agency.

Ms. VEVERKA. And it has cleared many of the hurdles, but we're putting it in its final publishable form. It then has to still go for clearance through the Public Health Service and through the Department, and I believe through OMB, correct?

Dr. KESSLER. That's right.

Mr. WALSH. How long do you expect it will be before it's made public?

Dr. KESSLER. Again, you learn in this town, Congressman, that you only commit to what you can commit to, and the only thing I can assure you is when it clears the Agency. I control that.

This is very important. I mean, this is really very important, and we have been working hard, and we want to certainly strengthen our animal drug program to its fullest.

Ms. VEVERKA. I can personally commit to faster than 30 days in the Agency.

Mr. WALSH. Great, thank you.

Mr. DURBIN. Bidding war.

Mr. WALSH. Pardon?

Mr. DURBIN. Bidding war.

Mr. WALSH. Yes, would anyone like to go 15? [Laughter.]

ANIMAL DRUG APPROVALS

Mr. WALSH. I'm sure you're aware about studies that have shown that the average time to approve an animal drug application is upwards of 50 months, and that's not acceptable.

I understand also that in about the last six years, there has only been eight new drugs admitted for animal health purposes, is that correct?

Dr. KESSLER. Let me let Dick, Dr. Richard Teske, comment, if it's okay, Congressman.

Mr. WALSH. Sure.

Dr. TESKE. I think, Mr. Walsh, there's a bit of a misunderstanding about that. In recent years, however, there have been reductions in the numbers of approvals going out.

I should say however, that in 1993, that was reversed, and we had the largest number of significant approvals for any one year since the inception of CVM.

Mr. WALSH. How many was that?

Dr. TESKE. Thirty-seven, I believe it was.

Mr. WALSH. So 37 approvals.

Dr. TESKE. Significant approvals. You know, there are many supplements and things we don't count in that number, but what we count is significant approvals—37. We think that that trend, although we don't hope to beat that record in 1994, that trend is continuing, and we think there will also be a very significant number of significant approvals in 1994.

So we think we've turned the corner that existed in the period say 1988 through 1992.

Mr. WALSH. The period of 50 months for 32 of those drugs ended in 1993.

Dr. TESKE. In the analysis we've done as part of this user fee feasibility study that's been undertaken by the agency, we noted that for the drugs that were approved in 1992, the average approval time was 50 months plus, and as you have indicated yourself, that's an unacceptable number to us as well as to the industry. In addition, the user fee analysis that we did identified some of those bottlenecks that caused that problem. That's part of what's gone into development of the kinds of commitments that we would be prepared to make to try to address those questions in the event that user fees would be approved to enhance the animal drug review process.

Dr. KESSLER. Congressman, there are a number of drugs like the one that the Chairman talked a little bit about earlier, BST. As you can see from the controversy surrounding it the American people want to make sure that we look at drugs like that very thoroughly.

In fact, that drug has been in, was under review how many years?

Dr. TESKE. Approximately ten years.

Dr. KESSLER. Ten years.

Mr. WALSH. Five for humans, five for animals.

Dr. KESSLER. I'm not sure of the exact number of months. We need to work on getting the number down. You are correct, but there may be some outliers in some of those numbers. We want to strengthen the program but when you are dealing with drugs for which people really want assurances that we have done our homework, like BST, the only way a product like BST is going to be able to be accepted is if, in fact, we do a very thorough review and can give the kind of assurances that it's safe, and that it had a thorough review. In this case, a ten year review.

You may look at that and say gee, you know, that's awfully long, and that in fact is a very long period of time.

Mr. WALSH. A company the size of Monsanto, for example, can probably handle that, although I'm sure they would tell us that they can't, in terms of the cost to them. It is my understanding

that some of the companies, if not all of the companies who do animal medicine are much smaller.

Dr. KESSLER. Right.

Mr. WALSH. And they can't survive. When all of their investment research and development goes into one product, they can't survive for four or five years.

Dr. KESSLER. And that's true as you and I have discussed for the medical device industry it is very important. There are different structures to the industry.

Unfortunately, we have to look only at the application, and it is irrelevant to us, even though we understand the importance, as to whether is it a big company or it is a small company.

Mr. WALSH. Right.

Dr. KESSLER. We just look at the data and the questions, and what it takes to answer those questions. So whether BST is from a small company or from a large company, we have to be blind to that during application review. Obviously the realities that you point to are very real, and that's one of the issues in the user fee analysis.

MEDICAL DEVICE REVIEWS

Mr. WALSH. Yes, I think it really does affect the marketplace, and you mentioned the medical device problems that we talked about that took several years. It was non-intrusive. It was not new technology. It was an improvement in existing technology.

That company made a decision that for their other products, rather than introduce them in this country, they would go offshore, manufacture that product and sell to the rest of the world, and not sell that technology in the United States because of the approval process.

While your depts credibility is certainly uppermost in our minds, the time it takes to approve new products is also critically important because you do affect the introduction of new science and technology, and if this process becomes too obtrusive then we start to lose our edge and we have to be sensitive to that.

Dr. KESSLER. Congressman, you were kind enough to point to some of the accomplishments as you started your remarks. One of the things, the only reason that I can do my job is because we have really wonderful, very skilled managers at the agency.

If I could just ask Dr. Burlington to respond to you a little on the medical devices.

Mr. WALSH. Sure.

Dr. KESSLER. So you can see some of the changes that he is trying, with his new leadership in the center for devices, over the last year since you and I've talked here. I think that you can see that we're working hard to address those kinds of concerns.

Mr. WALSH. Great. Go ahead, Doctor.

Dr. BURLINGTON. Thank you, sir. We have, in fact, taken very seriously the long times to review devices, and have put in place a number of management changes to try and deal more effectively with the huge volume of work that this vigorous industry is bringing us.

Some of those management changes are better communication with industry so that they will at least have a realistic business ex-

pectation of what to expect from us, but in addition to that, we have put in place a triage system where we're allocating our review resources according to the risk of the products.

If the products are in the lowest category of risk, we are giving them an administrative review. We are making sure they meet the standards, the voluntary standards that are publicly available. We're making sure that their labeling claim structure is appropriate, but we are reserving our full scientific review for the riskiest products.

In addition to the management changes in how we process applications, we have also looked at ways to reorganize the way we administer or have our staff organized in terms of flattening the program, reducing the number of stops that each application has to go through.

These changes have resulted in an impact. We've had a significant increase in output. In the first half of 1993, we were falling behind at a rate of about 100 applications a month for 510(k)s. We were getting 75, 80 percent of the work done, and the rest of it was not getting done, and it was building into backlog.

In the second half of last year, we drew even and actually had a slight surplus of work-out compared to work-in. In the first two months of this year, with new resources that this committee has had a major role in providing us, we have actually been able to do substantially better. We are now doing about 20 percent more work-out every month than we get in.

And these changes we hope are going to have a big impact but they are not the whole story. We have about a year of undone work to accomplish.

Mr. WALSH. That's welcome news. One issue that I know came up in this example, was that the submission of the application was held for a long period of time before it was kicked back to the manufacturer because it was not completed properly.

It would seem to me that that is something that could be easily handled by determining as soon as it is received whether or not the application process is in order, and then if it is not, go back to the manufacturer.

Dr. BURLINGTON. Yes, sir.

Mr. WALSH. Then they know where they stand.

Dr. BURLINGTON. Yes, sir, we became aware of that and I've been there about a year. One of the first things we did was put in place a quick evaluation to see if the applications were administratively complete against a checklist.

Not only do we look at that and turn them back to the manufacturer within 45 days if they are incomplete, we've shared those checklists with industry so that they can figure out how we're going to grade them before they even submit them.

Mr. WALSH. Good.

Dr. BURLINGTON. We think this is going to have a significant impact on our ability to turn things around more quickly.

MEDICAL DEVICE USER FEES

Dr. KESSLER. Congressman, if I could just point out.

Mr. WALSH. Yes.

Dr. KESSLER. If you look at the tremendous changes that Dr. Burlington has already made, and is trying to make, there is still a lot of time spent in queues, just waiting for the reviewer to open, certainly for the file review of the application.

We strongly urge your support, the Committee's support, and we would like to work with you on a way to strengthen that program even further. It's a very high priority, and the Medical Device User Fee program, I think could help eliminate those queues without reducing those standards.

I think in the end, just from a bottom line perspective, the price of a user fee would pale in comparison to the return that a company would have if it could get its product out there even just several months earlier.

We are committed, if there is a medical device user fee, to using those only for additional reviews for medical device products, and to committing to very strict performance standards that we would have to adhere to with regard to time frames.

We have the management in place. I think there is no question that additional resources to help strengthen that program is something that the administration is requesting in the 1995 budget, and we would like to be able to work with this Committee toward that.

Mr. WALSH. I understand your interest in the user fees, and I think in some instances, they are going to have a positive impact on your ability to return these applications.

I don't think, however, that more money is absolutely the solution to these problems.

Dr. KESSLER. It's not the only answer. You are correct on that.

MAMMOGRAPHY

Mr. WALSH. Lastly, if I could, I wanted to discuss something that comes up in the context of health care reform specifically the expansion of Medicaid to cover mammography could you briefly describe the benefits of mammography—it is my understanding that a mammography is beneficial over a certain age.

In other words, you don't want to utilize mammography too much because of the inherent risks in the use of that technology for women. Could you kind of give us an idea of your department's feelings on mammography and what age group should be using it, and what duration?

Dr. KESSLER. Let me turn you over to a real professional in the area.

Mr. WALSH. Okay.

Dr. KESSLER. You asked us, Mr. Chairman and members of the Committee, to implement a program to improve the quality of all mammography facilities. You set very strict time tables, in the law under that act, and we have had enormous good fortune to recruit Dr. Florence Houn, who is running the new mammography program.

She works in the breast screening program at Johns Hopkins as a physician. She still sees patients with that devastating disease. She's from the National Cancer Institute. Let me let her answer your question.

Mr. WALSH. All right.

Dr. KESSLER. And also maybe just tell you a minute about what the enormous challenge that she's facing to get this program up and running, because by October 1, 1994, all mammography facilities have to be certified or they can't be in business.

Dr. Houn.

Dr. HOUN. Thank you, thank you. It's a pleasure to have this opportunity to talk to the committee.

The Mammography Quality Standards Act is a wonderful piece of legislation to enforce cancer control, breast cancer control, and it's my extreme commitment to have this act fully implemented so that all women in the U.S. can benefit from quality mammography services.

I think the scope of the act is to provide women with that reassurance, that the mammogram they get is of the best quality, that the people involved in processing and producing that mammogram, and interpreting that mammogram, are of the highest quality, can provide the highest quality service to the woman who has the question.

I think your question about screening guidelines is, in fact, a very legitimate scientific and medical, controversial question. I think a lot of research still needs to be done in that area. It's obvious that there is a medical controversy. It's obvious that breast cancer is a serious and fatal disease, and it is understandable that women are very concerned about this, and are seeking mammography.

It is our job in the Food and Drug Administration to make sure that women who have mammograms, whether it's for screening purposes or diagnostic purposes, get the best quality mammogram.

So that is the commitment of the division as well as the center and agency.

Dr. KESSLER. Over 50, the guidelines are relatively clear.

Dr. HOUN. Over 50, there's a general consensus in the scientific community that women do benefit from mammography, and that's because the anatomy of the breast is different as women age.

As women age, the glandular tissue of the breast gets replaced by fatty tissue, and fatty tissue provides a better visualization in terms of contrast and resolution for radiography.

Women with glandular tissue, and younger women have glandular tissue with a lot of what appears on mammograms as dense breast tissue, and it looks very white compared to what we strive for as a light grey to look for contrast and resolution, a very white appearance of young breast tissue makes it difficult to detect lesions.

The sensitivity and specificity of mammography is lower in women with very dense breast tissue, and that's why there is controversy in terms of the efficacy of mammography for reducing breast cancer mortality in younger women.

MAMMOGRAPHY RISKS

Mr. WALSH. So it is not the technology that is of risk to those who utilize it—other than the inability of the equipment to interpret whether or not this is indeed a cyst or a tumor. But is there no risk to the individual who has this test in a regular interval?

Dr. HOUN. I think that the risk from mammography, if you are looking at risk, there are lots of different components. I think in the early 1970's the technology for mammography was miserable.

They used industrial-strength x-rays and the equipment was not suitable for mammography in terms of suitable risk/benefit ratio for radiation. I think with the new technology in the 1980's and especially now with new equipment with the image-receptor being replaced from molybdenum, to rhodium, there is an ability to detect an image at much lower doses of radiation.

The radiation risk I think is negligible. I think the risk that younger women have in mammography doesn't lie with radiation, but with image quality and consequences of misinterpretation because of dense breasts, and does it lead to further biopsies, further medical procedures because of questionable findings.

Mr. WALSH. Thank you for clearing that up for me.

Dr. KESSLER. Congressman, if we could just introduce for the record, Dr. Houn, the Mammography Matters Newsletter, because we are issuing this to all mammography facilities and providers in this enormous effort to get this program up and running, get everyone certified, get everyone up to standards that the American women can count on.

[The information follows:]

From FDA/CDRH to help facilities implement MQSA

MammographyMatters

Winter 1994

Volume 1, Issue 1

Welcome to Mammography Matters...

This is the inaugural issue of *Mammography Matters*. This quarterly publication is designed to inform mammography facilities and other interested individuals and groups about the program of the Food and Drug Administration, Center for Devices and Radiological Health, to implement MQSA. Our goal is to help you comply with this important Act by providing the information you need in a timely and accessible manner.

We plan to include articles about MQSA standards, advisory committee meetings, our mechanisms for communicating with facilities and the public, the federal/state facility inspection program, plans for issuing facility certificates, and other relevant topics.

You may reprint information in this publication without permission. We also encourage you to adapt the articles for publication in professional society or consumer journals and newsletters.

It is important to keep our lines of communication open if we are to help meet your needs. Please send us your questions and comments. Address any correspondence to: *Mammography Matters*, FDA/CDRH (HFZ-240), 5600 Fishers Lane, Rockville, MD 20857; Fax 301-594-3306.

We want to hear from you!

New FDA Regulations Affect Mammography Facilities

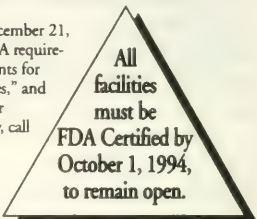
Have you become familiar with the recently published mammography regulations? It's important reading — by October 1, 1994, your facility must comply with these regulations if it is to remain open. You need to start now to be in compliance by the deadline.

FDA published the regulations in the December 21, 1993, *Federal Register* to implement the MQSA requirements. The regulations are titled "Requirements for Accrediting Bodies of Mammography Facilities," and "Standards and Certification Requirements for Mammography Facilities." If you need a copy, call our information line at 301-443-4190.

Must Be Accredited

MQSA requires that all mammography facilities, except those of the Department of Veterans Affairs, be accredited by an approved accrediting body (either a private, nonprofit organization or state agency). They must also obtain a certificate from FDA in order to legally provide mammography services after October 1, 1994.

These requirements apply to all facilities that produce, process, or interpret mammograms, whether for screening or diagnostic purposes.



All
facilities
must be
FDA Certified by
October 1, 1994,
to remain open.

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The Accrediting Body Regulation (Subpart A)

Subpart A, the accrediting body regulation, specifies the requirements that apply to accrediting bodies and how prospective agencies may apply to FDA for acceptance as an approved accrediting body. This subpart states that any approved accrediting body must:

- ▶ Enforce standards at least as stringent as those specified in the December 21, 1993, *Federal Register*.
- ▶ Perform reviews of clinical images from each facility.
- ▶ Evaluate annual physicist surveys from each facility.

Continued on page 6

From the Program Manager

Dear Colleagues:

These are exciting times for everyone concerned with breast cancer control and for those engaged in mammography. The Mammography Quality Standards Act of 1992 (MQSA) and the interim final regulations issued by the Food and Drug Administration (FDA) on December 21, 1994, usher in a new era of mammography quality in the United States.

MQSA represents the hard work of many people, including breast cancer patients and their families, cancer prevention and control advocates, researchers, physicians, and legislators. The support and efforts of Senator Barbara Mikulski (D-MD) and Congressman John Dingell (D-MI) have been extraordinary. Quality mammography has been and continues to be a uniting goal.

While FDA is working with the National Mammography Quality Assurance Advisory Committee to prepare final quality standards by 1995, others are engaged in a flurry of activity to make this initial implementation of MQSA a reality. State radiation control programs, FDA regional radiological health representatives and district x-ray auditors, consumer groups, and



professional organizations are all moving forward on this important effort.

Your facility's compliance with the quality standards outlined in the interim regulations that were mailed to you in January is the key to ensuring that quality mammography becomes more than just an ideal on paper.

We at FDA recognize that this period of transition to full implementation of MQSA is a confusing time. This publication will help you understand what your facility needs to do in order to meet the standards issued under MQSA. We want to serve you! Please feel free to suggest topics and even submit articles for future issues.

I cannot stress strongly enough how much we want to

assist your facility in complying with MQSA regulations and performing high quality mammography. This publication is just one of several efforts to help you reach this goal. For example, if you need copies of the regulations, the Act, and other written materials, please call our special information line at 301-443-4190. You can also Fax questions to us at 301-594-3306.

Let us hear from you so we can work together to achieve this important common goal.

Florence Houn

Florence Houn, M.D., M.P.H.
Program Manager, Division of
Mammography Quality and
Radiation Programs

Meet Dr. Florence Houn, Manager of New Mammography Program

Florence Houn, M.D., M.P.H. has been selected as program manager of the new Division of Mammography Quality and Radiation Programs in the Food and Drug Administration's Center for Devices and Radiological Health. Dr. Houn's division is responsible for implementing MQSA, the new law intended to help assure that women derive maximum benefit from mammography examinations by improving the quality of mammography services.

The new division is responsible for establishing and implementing minimum standards for the roughly 10,000 mammography facilities in the U.S., as well as for the personnel who perform these procedures. By October 1, 1994, facilities must be FDA certified as meeting the standards to remain open. The division will also approve the organizations that will accredit the facilities and will help train the federal and state personnel who will conduct facility inspections.

Dr. Houn is well prepared for her new responsibilities. After receiving her undergraduate degree at Harvard University, she studied medicine at the Albert Einstein College of Medicine, was an intern and resident at Columbia-Presbyterian Medical Center, and obtained a Master of Public Health degree from Johns Hopkins University.

Dr. Houn is board certified in internal medicine and has performed research on breast cancer prevention and early detection at the Division of Cancer Prevention and Control at the National Cancer Institute (NCI), a component of the National Institutes of Health. Part of Dr. Houn's research at NCI focused on the organization, delivery, and clinical outcomes of mammography services in the U.S.

She is also a clinical fellow in the Breast Surveillance Service of the Johns Hopkins Oncology Center. Dr. Houn has both clinical and management experience, having spent four years at Baltimore Medical System's primary care clinics prior to her work at NCI.

"I'm looking forward to this new challenge, and feel honored to be part of this bold effort to improve the quality of our mammography examinations nationwide," stated Dr. Houn. "It's exciting to be working with the facilities, the state radiation control program directors, the regional radiological health representatives, and others on this important common goal."



Where Can I Find the Mammography Regulations?

The regulations have been made part of the Code of Federal Regulations (21 CFR Part 900) and were printed in the December 21, 1993, *Federal Register*, Vol. 58, No. 243, pages 67558-67572.

A copy was mailed to mammography facilities in early January, but if you need another copy, Fax your request to 301-594-3306 with your name and address, or call 301-443-4190.

Nuts and Bolts of the Facility Certification Program

MQSA requires that all mammography facilities in the United States must be certified by FDA as providing high quality mammography by October 1, 1994. An accrediting body will provide FDA with proof that a facility meets the necessary requirements for certification. (An accrediting body is a private, nonprofit organization or state agency that has been approved by FDA to accredit mammography facilities.)

Procedures

The certification procedures, outlined in the December 21, 1993, interim facility regulation, include:

- ▶ Mammography facilities must prominently display a certificate or provisional certificate issued by FDA. A provisional certificate will be issued to a facility that has applied to a private or state accrediting body for accreditation but has not yet received it.
- ▶ FDA may issue new certificates or renew existing ones; these will be effective for up to three years. Provisional certificates may remain in effect for up to six months, with a one-time 90-day extension available for extenuating circumstances.
- ▶ Facilities are not generally required to provide FDA with any information that has been previously supplied to the accrediting body.

- ▶ If an organization or state applies to FDA for approval as an accrediting body and is approved, the facilities already accredited by this organization will qualify for automatic certification. This is true only if the standards under which the facilities were accredited are substantially the same as the MQSA standards.

Of Special Note

- ▶ Facilities should NOT apply directly to FDA for certification. FDA will issue certificates based on information received from the body that has accredited the facility.
- ▶ Unaccredited facilities should contact an approved accrediting body to learn what they need to do to become accredited. FDA will announce names of approved accrediting bodies as soon as they are selected.
- ▶ FDA will cooperate with the states, professional organizations, and mammography facilities to make sure the final certification program will not unduly burden the facilities.

The Bottom Line: Steps Facilities Must Take To Remain Open After October 1

To operate lawfully after October 1, 1994, your mammography facility must:

- ▶ Meet federal quality standards, as outlined in subpart B of the regulations.
- ▶ Receive accreditation by a federally-approved private nonprofit or state accrediting body. FDA expects that the American College of Radiology will be able to apply for and receive approval from FDA as an accrediting body. Some state agencies may also be able to meet our standards for accrediting bodies. FDA will announce the names of approved accrediting bodies as soon as they are selected.
- ▶ Be issued an FDA certificate stating that the facility meets the MQSA quality standards. The accrediting body will provide FDA with proof that the facility meets the standards. FDA will then issue the certificate directly to the facility. (See "Nuts and Bolts of the Facility Certification Program," left)
- ▶ Display the certificate prominently and continue to practice high quality mammography in accordance with the standards. Annual inspections by FDA-certified state or federal inspectors for compliance with the standards will begin after October 1, 1994.

FDA Commissioner Discusses Mammography Standards at RSNA Meeting

On December 1, 1993, in Chicago, FDA Commissioner David A. Kessler, M.D., invited over 3,000 people at the Radiological Society of North America (RSNA) meeting to join with FDA in working to make the early detection of breast cancer a reality.

"The toll of breast cancer is a call to action for all of us," Dr. Kessler said.

Regulations Explained

Dr. Kessler announced the imminent publication of the interim final regulations (see "New FDA Regulations Affect Mammography Facilities," page 1), noting that the agency will rely heavily on approved private, nonprofit or state accrediting bodies to assure that mammography facilities maintain the quality standards established by the regulations.

Annual inspections by FDA personnel or state inspectors, Kessler said, will help assure that the standards continue to be met. He stressed that after October 1, 1994, mammography facilities that have not received FDA certification will not be allowed to remain open.

The mission of MQSA, Kessler said, is "...mandated by Congress and

demanding by our professional standards. It is the right thing to do."

"Together," he continued, "we can produce mammograms that will be as revealing and reliable as human skill, specialized equipment, and medical expertise can make them."

This is the goal of MQSA...to give every woman who undergoes mammography the most accurate answer to her question about cancer."

"The toll of breast cancer is a call to action for all of us."

—Dr. David A. Kessler, M.D.
FDA Commissioner

Public Outreach

An impromptu press conference following Dr. Kessler's speech received national coverage.

Also at the RSNA meeting, more than 700 attendees participated in a focus session on mammography, and FDA personnel staffed an exhibit to further publicize MQSA plans and requirements. More than 1,000 visitors stopped by to discuss their views on implementing MQSA.

Call FDA To Request MQSA Information Packet

FDA has established a special telephone line that will allow you to request an information packet relating to MQSA (at this time, the packet consists of the December 21, 1993, *Federal Register* and our publication). The number is 301-443-4190. When you hear the menu, press 1 and then immediately press 8 to receive the packet and be placed on our mailing list. Leave your name and address at the prompts.

If you have specific questions regarding MQSA, you may Fax them to us at 301-594-3306.

New FDA Regulations

Continued from page 7

- ▶ Conduct on-site inspections of a small sample of facilities.
- ▶ Establish a reasonable fee structure.

The Facility Regulation (Subpart B)

Subpart B, the mammography facility regulation, covers the following topics, which will be explained in more detail in future issues of this publication:

- ▶ Health professional training, licensing, certification, experience, and continuing education for technologists, interpreting physicians, and medical physicists.
- ▶ Use of x-ray equipment specifically designed for mammography.
- ▶ Maximum radiation dose that may be delivered during routine mammography procedures.
- ▶ Quality control procedures for the equipment and image interpretation process at each facility. These include an annual survey, consultation, and evaluation by a certified or state-licensed/approved medical physicist.
- ▶ Recordkeeping, including:
 - Preparation of a written report of the results of any mammogram.
 - Distribution of results to the physician or patient.
 - Maintenance of the mammograms and reports in the permanent patient records for specified time periods.

Toward the Future

The regulations are "interim regulations" that will become effective on February 22, 1994. After FDA has consulted with the National Mammography Quality Assurance Advisory Committee and considered comments received on the *Federal Register* notices, it will develop and issue more comprehensive final regulations to replace the interim regulations.

First MQSA Advisory Committee Meeting

The first meeting of the National Mammography Quality Assurance Advisory Committee was scheduled for February 17 and 18, 1994, at the Holiday Inn Metro Center, 775 12th Street, Washington, D.C. Officials of the Department of Health and Human Services and a member of Congress involved in the passage of MQSA have been invited to speak at the opening session.

Advisory Committee

The advisory committee is comprised of 19 individuals—physicians, practitioners, and other health professionals whose clinical practice, research specialization, or professional expertise include a significant focus on mammography. Four of the members represent national breast cancer and consumer health organizations.

The individuals chosen bring geographic and professional diversity to the committee. Dr. Elizabeth Patterson, Assistant Professor of Radiology at the University of Pennsylvania and a nationally recognized expert on breast screening techniques, has been selected to chair the committee.

Committee Responsibilities

The committee is required to meet quarterly for three years and at least semiannually thereafter.

Committee responsibilities include:

- ▶ Advising FDA on the development of quality standards and regulations for facilities.

- ▶ Advising FDA on appropriate standards and regulations for accrediting bodies.
- ▶ Advising FDA on the development of regulations with respect to sanctions.
- ▶ Assisting in the development of procedures for monitoring compliance with the standards.
- ▶ Assisting in the establishment of mechanisms to investigate consumer complaints.
- ▶ Reporting on new developments concerning breast imaging.
- ▶ Determining if there is a shortage of mammography facilities in rural areas.

Meeting Agenda

At the February meeting, the committee was to review and comment on the interim final standards that were published in the *Federal Register* on December 21, 1993.

FDA staff was to report on the status of various projects, and the committee was to rank the tasks assigned to it by Congress in MQSA.

The meeting included an open public discussion where interested parties could comment on the interim final regulations and other matters relevant to implementing MQSA.

Q & A

"Questions and Answers" will be a regular column in Mammography Matters. We welcome your questions and will publish answers to any that are of general interest. Send your questions to: Mammography Matters: FDA/CDRH (HFZ-240), 5600 Fishers Lane, Rockville, MD 20857. Fax 301-594-3306.

Q 1. I have a mammography unit in my office that was placed there under an agreement with a service company for the benefit of my patients. Neither the x-ray machine nor the technologist who operates the unit are under my authority. The images are read by the company's radiologist who provides me with the results. Must I have an FDA certificate for this mammography unit?

A Yes. All mammography facilities must receive a certificate from FDA before October 1, 1994, or they will be in violation of federal law. Any mammography conducted in uncertified facilities will be unlawful and subject to penalties. You and your service company need to address this issue to assure that your patients are properly served. Unless the facility prominently displays the FDA certificate, patients, inspectors, and others may assume the facility is operating unlawfully.

Q 2. As a family practice physician who refers her patients for mammography, how can I determine whether the facility to which I refer my patients has been properly certified?

A Between now and October 1, 1994, mammography facilities that have been properly accredited will begin to receive their certificates. After October 1, 1994,

you can determine whether a facility is certified by checking to see if it has an FDA-issued certificate prominently displayed on the premises.

Q 3. I am a surgeon and use a mammography unit to evaluate patients and plan surgeries. Does my facility require an FDA certificate?

A Yes. All mammography facilities must receive a certificate from FDA. Unlike the Medicare mammography screening program, MQSA requires certification for facilities whose units are used for diagnostic as well as screening purposes.

Q 4. Our mammography unit is within a hospital that has been accredited by JCAHO. Will we be required to have an FDA certificate as well?

A Yes. All mammography facilities must receive a certificate from FDA. To receive a certificate, the facility must first be accredited by an approved accrediting body. FDA will approve any private, nonprofit or state body that can demonstrate substantial compliance with the accrediting body standards. These standards require that clinical images be reviewed by qualified personnel. At this time, it is our understanding that JCAHO does not substantially meet these requirements and could not be approved as an accrediting body under MQSA.

Q 5. We use mammography units in our training program for technologists. Does our training facility require an FDA certificate?

A It depends. Assuming that your training involves the examination of patients, rather than using strictly simulations or phantoms, your facility would be considered a mammography facility and would need a certificate. If no live human subjects are ever exposed with this equipment, it would not be considered a mammography facility and would not be subject to the requirements of MQSA.

Q 6. As a radiologist, I am part of a group practice that interprets mammograms sent to us by other facilities under a contract arrangement. We do not own the facilities that produce and process the mammograms. The only administrative control we have is indirect, such as when we reject a mammogram because of inadequate quality. Must my group have an FDA certificate?

A Yes. MQSA states that any facility that produces, processes, or interprets mammograms after October 1, 1994, must have an FDA certificate to continue to operate lawfully.

Errors in Mammography Regulations

We have found two typographical errors in the interim final mammography regulations published in the December 21, 1993, *Federal Register*.

1. Page 67563, first column, section 900.2(f). The definition for inter-

preting physician references section 900.14(a)(1). It should reference section 900.12(a)(1).

2. Page 67572, first column, section 900.12(d)(1). The last sentence should read "quality assurance," not "quality insurance."

Thank You

Thanks to Susan Gerhold of the Office of Management Services, Center for Devices and Radiological Health, FDA, who suggested the name *Mammography Matters* for our publication.

Mammography Matters is a quarterly

publication published by the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health (CDRH), Food and Drug Administration. Its purpose is to help mammography facilities comply with the requirements of the Mammography Quality Standards Act of 1992. It is distributed to mammography facilities and other interested

organizations and individuals.

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USER FEES

Mr. WALSH. Do you believe that specific process improvements with performance standards should be expected if user fees are assessed on any FDA regulated industry?

Dr. KESSLER. I believe that if the fees being assessed on industry are additive, as they were in the case of the Prescription Drug User Fee Act, then it is reasonable for the additive fees to be based on some new and mutually agreed upon expectations about what performance levels should be achieved with the additional resources.

Mr. WALSH. Should those process improvements and performance standards be placed in the public record or public law through committee reports or actual legislative language?

Dr. KESSLER. I also think it is reasonable for such performance goals to be made public, as they were in the case of the Prescription Drug User Fee reports, which included the goals for performance improvement. I prefer that such goals not be incorporated in statute, however. We are committed to following this same process with respect to the proposed Medical Device User Fees and have been meeting with industry representatives on appropriate goals.

Mr. WALSH. Energy and Commerce Committee Chairman Dingell recently stated that he did not believe that funds collected from FDA-regulated industries should be diverted to deficit reduction. He clearly stated that any user fees collected from industry should go specifically to speeding the FDA approval process. Do you agree with Chairman Dingell's comments?

Dr. KESSLER. The President's budget proposes new additive user fees for medical devices, and a continuation of additive user fees for the drug and biologic review process, as well as \$228 million in new user fees to maintain current FDA activities.

PRESCRIPTION DRUG USER FEE ACT

Mr. WALSH. How effective has the implementation of the Prescription Drug User Fees Act been?

Dr. KESSLER. We believe that the implementation of this Act has been very effective, and we are proud of our performance to date. Regarding the recruiting goal set out in the letters, we are on target. We have about 180 more FTEs on board now dedicated to the process for the review of human drugs than we had in 1992, before the passage of the Act. We are continuing to recruit aggressively, and incrementally our on-board staff dedicated to this process should exceed 350 by the end of this fiscal year.

Backlogs of overdue original new drug applications were reduced from 35 to 6 in our Center for Drug Evaluation and Research, and from 9 to 3 in our Center for Biologics Evaluation and Research, as of January 31, 1994.

The real impact of increased review staff on review times will take a while to show, as it cannot be measured until applications submitted each year have been acted upon. It also takes time to train new staff before they are fully productive in their work. We do have every reason, however, to expect continued improvement consistent with the Prescription Drug User Fee Act goals.

Mr. WALSH. What percentage of funds are going toward activities geared to improving the FDA process so that quicker approval of drug products is achieved?

Dr. KESSLER. With respect to your question about the use of the money collected under this Act, I assure you that it is going only to those things that enhance the review of drug and biologic applications, as called for in the Act. Naturally, this includes some administrative and overhead support, as we hire additional personnel and put new fiscal procedures into place, but that kind of support is allowed by the Act. We developed procedures to account for the use of fees collected under this Act, and we had Arthur Andersen and Company advise us on the reasonableness of these procedures. We will be publishing a report to Congress soon that explains the receipts and use of fees collected in 1993, and I will be glad to share it with you.

Mr. WALSH. There is a great deal of concern that much of the user fee money provided to the FDA so far has been used for administrative or surveillance purposes. Can you comment on this?

Dr. KESSLER. Monies that are not used for the purposes described in the Act are carried forward for use in future years; they are not spent on things not allowed by the Act. None of these monies have been used for surveillance, or for any other purpose not intended by the Act and its legislative history.

Mr. WALSH. How will the National Performance Review's requirements to downsize GS 14 and 15 personnel affect the FDA's inspection responsibility in other areas for instance inspection obligation of industries other than prescription and medical devices, i.e. food to protect public health and order?

Dr. KESSLER. We expect to comply fully with the letter and spirit of the National Performance Review mandate to carefully review and reduce the number of supervisory and managerial personnel. We believe that this can be accomplished in the majority of FDA's activities including inspections without any lessening of the protection we provide for the public health. It challenges us to be more creative and efficient in how we work and how we serve the American public.

Mr. DURBIN. Let me just say, and I'm going to recognize Mr. Myers next, this has been one of the highest priorities of this subcommittee. We were given good legislation to inspect these clinics and make sure that the women who go in there can leave assured that the results that they have been given are something that they can rely on for their own personal health.

We've gone to battle within Congress, within the Administration to make sure that Dr. Houn and the FDA can meet the important deadlines that have been set. I think that history will judge this as a good investment of taxpayers' dollars.

Mr. Myers.

MAMMOGRAPHY GUIDELINES

Mr. MYERS. Thank you, Mr. Chairman. I regret that I had to leave for a little while here, but next door we had a defense hearing and that's very important, too, to the safety and security of our families and our country, so I had to go in there for a few moments.

But following up on the question about mammography, it's my understanding that the final decision as far as guidelines has not been fully drawn, is that correct?

Dr. KESSLER. Mr. Myers, let me just make one thing clear to the Committee, because I don't want to put Dr. Houn on the spot too much. She runs FDA's mammography program, which is striving to make sure that the way the mammogram is taken and the qualifications of the people who provide the service are really up to high standards.

The issue on guidance to women based on age and how often and when mammography is recommended is really within the province of the National Cancer Institute. We would be happy to provide our input to your question, but we shouldn't be speaking for the National Cancer Institute.

Mr. MYERS. No, I didn't mean to ask that question, but what about the guidelines for your screening facilities?

Dr. KESSLER. Oh, our guidelines to the technicians.

Mr. MYERS. To the technicians.

Dr. KESSLER. Right.

Mr. MYERS. Have you drawn those completely now?

Dr. HOUN. The agency has issued interim regulations, and they became effective February 22nd. The final regulations are being developed with our National Mammography Quality Assurance Advisory Committee, and the first meeting of this committee was February 17th and 18th, where we discussed personnel requirements for the medical physicist, the technologist, and the interpreting physician, as well as for accrediting bodies.

So in terms of drawing up final regulations, our goal is to have them out by October, 1995. The interim regulations are in effect now, and our plan is to begin annual inspections in October of this year.

Mr. MYERS. So it's going to be impossible to meet the guidelines Congress has given you for the—

Dr. KESSLER. No, no, let me just amplify. We did issue at the end of last year interim final rules. I apologize for all these terms.

Mr. MYERS [continuing]. We understand that. We've been on the Committee a year to two.

Dr. KESSLER. The interim final rules that were issued in December of 1993 went into effect for all intents and purposes, Congressman. Let's call those the final rules for this round of certifications. They went into effect on February—

Dr. HOUN. February 22nd, and I have a copy of them for your record. In the interim final regulations there are guidelines for personnel qualifications, for dose, radiation dose limits, for type of equipment used, for quality control procedures.

The reason why we're calling them interim is that they were not developed with our National Mammography Quality Assurance Advisory Committee, and some issues we did not have time to address in terms of specific regulations which we would like to have for mobile units.

We would like to issue specific regulations for women with implants and how to best image them, but I think in terms of wanting to get out some very fundamental, yet very important safety

net standards for the Nation, we have published them, and they are in effect.

Dr. KESSLER [continuing]. And what we're working with with the advisory committee is to upgrade, to fine-tune those interim finals, to make them even better in years to come; but there should be no mistake, all mammography facilities will be judged against those interim finals.

Mr. MYERS. Well, we know that mammography starts with the equipment being used, and then next, of course, the technician who applies that device, and then very importantly, the radiologist who reads it, and those three ingredients are just vitally important.

Today under the interim rules that you have drawn up, can the old style of x-ray, the old-fashioned heavy-dosage x-ray still be certified?

Dr. HOUN. No.

Mr. MYERS. Good.

Dr. HOUN. It cannot.

MAMMOGRAPHY QUALITY STANDARDS ACT

Mr. MYERS. You are proposing to collect \$6.5 million in user fees for the Mammography Quality Standards Act. Is this amount in addition to an appropriated request to fund your responsibilities under the Act?

Dr. KESSLER. The Mammography Quality Standards Act of 1992 directs the Agency to assess and collect fees for inspections of mammography facilities. I should point out that there are many other costs that the Agency will not be permitted to charge for under that act, such as our costs of certifying facilities, the costs of reinspection, and the costs of inspections of government operated mammography facilities.

FDA expects to collect \$6.5 million in inspection fees in FY 1995 but will pay for the costs of these inspections with appropriated funds in 1995, rather than from fees collected. This will allow FDA to capitalize this fund in 1995 with receipts collected, so there will be funds available in 1996 to begin paying these costs.

Mr. MYERS. When will the Act be fully funded?

Dr. KESSLER. As we implement MQSA, FDA will have a more complete understanding of the resources needed to fully carry out the Act. At present, we estimate there are 14,225 mammography facilities nationwide. This is a 40 percent increase from the 10,000 facilities estimate used in 1992 when MQSA was established. This increase in the number of facilities is part of the trend since 1987 of a logarithmic rise in the number of mammography machines.

In addition, the Act defines mammography facilities to include partial providers of mammography services, such as processing-only or interpreting-only facilities. FDA realizes that the increase in numbers of facilities requires more inspectors to be trained and more inspection equipment to be acquired. We also realize that we will not be able to collect inspection fees—user fees—from governmental facilities, and the fees we are allowed to collect can only cover the cost of inspection and not other program activities. Furthermore, we anticipate some facilities will cease mammography services.

Mr. MYERS. How many facilities nationwide will be accredited in 1995?

Dr. KESSLER. We hope all facilities will seek accreditation and be certified in 1995, but estimates of that number will be elusive until we and the States begin the inspection program, which will begin October 1, 1994, and see the impact of MQSA.

BORON NEUTRON CAPTURE THERAPY

Mr. MYERS. Okay. I think there are still quite a few in the country in rural areas especially. I'm shocked when I go out to Indiana and find some who are still depending upon the heavy-dosage, not getting the complete breast, and the technician who wouldn't know an x-ray from a picture of a cow, quite honestly.

I have personal experience along that line and it shocks me that it is still going on. That's one of the reasons we are pushing it in this committee. I am going to help with this committee and members here, and you and I have talked about this a number of times.

I appreciate the job you are doing here. It is just vitally important that we do make sure that women go in and pay their money and can depend on the mammogram, that they get quality treatment and quality assurance that somebody qualified looked at that film.

Okay, that's enough of that, I think. Again, if there is something that comes up that you have already considered, well, please tell me and I can read the record too. It will save your time.

One of the concerns that I have is boron neutron capture therapy for treatment of someone with a brain tumor particularly. What role do you play on this therapy, if any? The Agency?

Dr. KESSLER. Why don't I ask Dr. Lumpkin specifically on that therapy.

Mr. MYERS. Okay.

Dr. KESSLER. I will let him talk about it. He is deputy in our Center for Drug Evaluation and Research.

Mr. MYERS. Well, that's the other committee. Of course, the DOE would provide the equipment, but then—

Dr. KESSLER. Right. Dr. Lumpkin can explain the role of his center and also maybe point out a little bit about our Center for Devices and Radiological Health.

Dr. LUMPKIN. Yes, sir.

Mr. MYERS. Is that right? Okay.

Dr. LUMPKIN. Yes, sir. Congressman, the technology that you have spoken about is a technology that would fall within the jurisdiction of the Center for Drugs, at least a part of that technology would.

I think I would hasten to say here that the Center would be very happy to share with you, and with an appropriate committee, the details on that. But I have been cautioned about the trade secret provisions of our act—which prohibit the release of information submitted with a new drug application concerning any method or process which as a trade secret is entitled to protection—that this would not be an appropriate time to go into detail. We would be happy to share the information in response to an authorized request from the subcommittee.

Mr. MYERS. Well, I'm not asking for chemical diagnosis.

Dr. LUMPKIN. Okay.

Mr. MYERS. Of the boron compound. I'm just asking what procedure, what right and obligation and responsibility that you have.

Dr. LUMPKIN. The procedural right would be such as Dr. Kessler pointed out earlier. There is a component of that technology that is regulated as a drug, and whoever wanted to do that particular procedure, as with any other kind of drug, would be required to first study it. If they wanted to study it in this country, it would be done under the auspices of an IND. When the sponsor felt that there was sufficient data to show that it was a safe and effective utilization of a drug, to come out with a good clinical purpose, then the sponsor would submit a new drug application, and we would review it within the Center for Drugs.

Mr. MYERS. But what you have told us here, I guess there has been no application made, no consideration at this point of the compound.

Dr. LUMPKIN. I don't think I can answer that question at this point under our restrictions on releasing confidential commercial and trade secret information.

Dr. KESSLER. We apologize, Congressman.

Mr. MYERS. There is no trade secret about that. Japan uses it all the time. We've got patients who go to Japan to be treated.

Dr. KESSLER. Congressman, we would be happy to work with you privately. We are not trying to be difficult. We run into this problem all the time.

Mr. MYERS. It sounds like it.

Dr. KESSLER. And again, I would be happy to work with you privately and to sit and talk. There are certain restrictions in the statute and in our public information disclosure regulations that just prohibit us from talking about specific applications.

It makes us sound like we're being difficult and obstreperous. In fact, the restrictions are in the statute and regulations. So if there is a way that we could work with the Committee to make sure that we just don't do something improper, that's what we're trying to do.

Mr. MYERS. You see, this is one of the problems we have up here all the time—flim-flam, back and forth, I can't do it, it depends on you, and you say, no, I can't do it because it's a trade secret.

Consequently, nothing gets done. We have patients that testified before the other committee that their life was saved because they went to Japan and were treated. Next week we'll have several patients in that category, while you people worry about some trade secret.

Dr. KESSLER. Please Congressman, understand, we are concerned about following what's in the statute, and if there is an application before the Agency, and it is in the investigational stages, we can't talk about the status of that unless the manufacturer has already talked about the status, or we are in violation.

Mr. MYERS. You don't come under the freedom of information statute.

Dr. KESSLER. Under—

Mr. MYERS. Are you being exempted from it?

Dr. KESSLER. Again, we would be happy to work with you. We are precluded from talking about applications that are in the investigational stage, unless the manufacturer allows us to do so. I

would be happy to talk about it, and there are ways to work with the Committee. We just don't want to violate the statute.

Mr. MYERS. That's what I'm asking you about.

Dr. KESSLER. We find ourselves in this issue a number of times when patients want access to information. Most of the times, the drug companies give us the ability to talk about it, and maybe we can work that out here. That just frees us up.

During the investigational phases of drug development, we may not talk about specific applications because existence of an application is the property of the sponsor and goes to the competitiveness of firms that submit applications.

If I start talking about those without the company's permission, I could be in violation of the statute and regulations. That's the only problem.

Mr. MYERS. Can you talk in generic terms then?

Dr. KESSLER. Sure.

Mr. MYERS. What jurisdiction does your agency have over the Department of Energy's Boron Neutron Capture Therapy program? Have you reviewed any application for clinical trials of the BNCT compound?

Dr. KESSLER. We do not have jurisdiction over the compounds used in boron neutron capture therapy under section 505b of the Food, Drug, and Cosmetic Act. Regulations on confidential commercial information prevent us from divulging whether or not we have received any Investigational New Drug applications for these compounds.

Mr. MYERS. Are there any reasons you have seen so far that would indicate you could not approve this treatment for certain types of cancer?

Dr. KESSLER. The regulations also prevent us from discussing any data that would be submitted in an application for the treatment of cancer.

Mr. MYERS. Have you reviewed the experiences other nations, such as Japan, have had using this treatment successfully?

Dr. KESSLER. We have not had the opportunity to review data on the success of this therapy in Japan.

NEW DRUG DEVELOPMENT

Mr. MYERS. I had a pharmaceutical company in the other day and we asked them about new drugs and the orphan drugs and all this, and I asked them about new drugs coming on the market.

A year ago they had eight studies developing, working towards making an application. Today they only have five, and I said well, did three of them advance into clinical phases? No, we dropped them. Why? Because the impending legislation on health care, there may not be the advisability for them to make the investment.

Is that typical of what's happening with new drugs in this country? We know Canada hasn't developed a new drug in the last 12 years. We know we're producing 50 percent of the new drugs. You had 300-some approved this past year. That's 50 percent of the world's research.

Are we going to find ourselves where there will be no place to go? They can, the Canadians can come down here now to be treated

because we are still developing new drugs. What's going to happen if we aren't going to be producing them here?

You're not going to be producing them, the private sector is, aren't they?

Dr. KESSLER. Absolutely. You are correct that drug development is done in the private sector. Sometimes our colleagues at the NIH play a major role, but we do not manufacture drugs. We are very dependent on the private sector to do that.

In my opening statement, I talked about two important drugs. I talked about DNase for cystic fibrosis. That really has enormous potential, the first drug in many years to treat cystic fibrosis—an enormously important drug, and also betaseron for multiple sclerosis.

The issue of health care reform, I think, needs to be placed in perspective. The President's plan covers prescription drugs for everyone. That is, if I were a pharmaceutical company and somebody told me that all drugs were going to get paid for, boy, I would be developing a lot of drugs.

Now, I think the issue that we all face is how are we going to pay for drugs and not run out of money. We are going to have to come up with some ways, if drugs are going to be paid for, to be able to control costs, and that's the issue.

I think everybody in all the pharmaceutical and biotech companies that I've talked to, understands that drugs are going to be covered. It's going to be. In the end, there is going to have to be some way that we are going to be able to afford those costs.

The question is how. The President, his Administration, and his health care advisors have gone through a number of different options. The first issue was price controls on drugs and the pharmaceutical industry said that they found those objectionable, so those were taken out, they were struck from the plan.

Then there was the issue of national formularies, and people felt that was too restrictive. There is the issue of negotiating on medicare on the price of new drugs. Again, it is not within our province, per se. I stay out of the drug pricing issue.

Mr. MYERS. I think we should too.

Dr. KESSLER. The Administration understands that if drugs are going to be covered, and if the Administration hasn't gotten it right, on how to cover drugs and still be able to afford it, if there is a better way, I think the Administration is open to it.

Mr. MYERS. Okay. All of us are concerned. I have to make sure that we do continue to be on the leading edge of developing new drugs.

Dr. KESSLER. Absolutely.

Mr. MYERS. And that's one thing why we are looking at other countries who have socialized their medicine, what has happened to the pharmaceutical industry.

Dr. KESSLER. Right.

ANIMAL DRUGS

Mr. MYERS. And I am not making any case for the pharmaceutical industry, but let me follow up from Mr. Walsh.

As I understand under the animal drugs, that you are required to make a decision within six months. Am I wrong about that?

Dr. KESSLER. It's 180 days.

Mr. MYERS. Okay, 180 days. Yet you say five years. Why does it take five years when you are under a mandate to make a decision within 180 days from the application?

Dr. KESSLER. Again, I think it would be unrealistic for us to review an application like BST and to assure the American public that something like that is safe and effective without the kind of review that we went through on that.

You see, even with that review, even ten years of study, even of the most extensive analysis by advisory committee after advisory committee, and the best scientists, there are still those that question that decision.

We've tried to be thorough. In the end, yes, the clock is important to us. We are trying to get user fees so we can reduce those times, but in the end, you and I both agree that we shouldn't be making any decision before we're sure that the facts are there.

The user fees really would allow us to get the time down, but not by reducing standards. If there are a lot of applications in front of you, the best way to keep the standards up and yet allow people to speed up review, is to have the time in queue reduced.

It's like the motor vehicle line. It's like going to the line in the motor vehicle place. There are a lot of people in line, and when you finally get up there, many times your time is not that long. Sometimes you are waiting a lot in the review system, but money is not the only answer.

There are a lot of different management changes that Dr. Burlington has alluded to, but sometimes you've just got to open up a couple of more lanes to review. There are a lot of different ways to approach that problem.

Mr. MYERS. Current law mandates a decision to approve an animal drug application in six months. What is the average length of time it takes FDA to approve an animal drug application? On the average, how many submissions does it take until an animal drug application is approved?

Dr. KESSLER. The Center provides a decision on approval to the sponsors of animal drug applications within six months about 75 percent of the time and within a few weeks in the remaining 25 percent of the cases. This is, however, only one cycle in the approval process. The Animal Drug User Fee Feasibility Study examined the process in detail and discovered that it is taking more and more cycles to get an approval each year. These increasing cycles also mean that more and more submissions are required to obtain an approval. I will be happy to provide information for the record on the average approval times for animal drugs.

[The information follows:]

AVERAGE APPROVAL TIMES FOR ANIMAL DRUG APPLICATIONS

The table below shows the calendar months, number of cycles, and number of submissions it has taken to get an approval for each of the last six fiscal years.

	Fiscal year--					
	1988	1989	1990	1991	1992	1993
Average calendar months to approval	33	41	47	42	54	59

	Fiscal year—					
	1988	1989	1990	1991	1992	1993
Average number of cycles to approval	1.9	2.3	3.0	3.6	6.3	5.8
Average number of submissions needed for approval	5.2	8.3	9.7	11.3	17.0	26.0

DRUG APPROVALS

Mr. MYERS. I think if it takes so long to develop the criteria or run the clinical trials, more people aren't going to help that any except maybe you get more people working on more drugs, is that what you're saying?

Dr. KESSLER. Again, it's very complicated. How long do you think it takes today for the Agency to approve an AIDS drug?

Mr. MYERS. That's what I was going to ask you, the difference on animal drugs as well as—

Dr. KESSLER. Right.

Mr. MYERS. Human drugs.

Dr. KESSLER. Human drugs. The average time for an AIDS drug today is—I wish I had more applications in the Agency, we don't have enough applications to the agency to review—the average time was about 12 months in FY 1993.

Mr. MYERS. For animal drugs.

Dr. KESSLER. For AIDS drugs.

Mr. MYERS. Oh, AIDS, okay.

Dr. KESSLER. For AIDS drugs. If you look at cancer drugs, something that you and I have talked about over the years, the average time for an oncology drug was about 11 months in FY 1993.

Mr. MYERS. Why don't you just provide that to the record, would you please? I hate to take the time.

Dr. KESSLER. Sure.

[The information follows:]

There were three cancer New Drug Applications—NDA's—approved in FY 1993. The average approval time for those cancer NDA's was 11.6 months. Among the cancer NDA approvals was Taxol which took 5.3 months for approval. There were three AIDS-associated NDA's approved during FY 1993. The average approval time for those AIDS-associated NDA's was 12.6 months. The average approval time for the cancer and AIDS-associated NDA's in FY 93 was 12.15 months.

The AZT NDA was approved in FY 1987. The approval time for the AZT NDA was 3.5 months. In FY 1991, an AIDS NDA—Videx—was approved in 6 months.

Mr. MYERS. What status is RU-486?

Dr. KESSLER. The Agency has said that if there is a safe and effective medical alternative to a surgical procedure, then it should be made available in this country. There are negotiations underway between the population council and Roussel-Uclaf, and its parent company, Hoechst, but again, as we just discussed, somebody needs to submit an application to the Agency and then our job is to review that application.

There is no application that has been submitted to the Agency.

Mr. MYERS. Case by case then today, is that right? There has been no clinical trials.

Dr. KESSLER. No I'm sorry. There's been no application that has been submitted to the Agency. There are extensive clinical trial data, especially in those countries where the drug is in widespread use.

Mr. MYERS. You can't accept that. Many times you have told us you don't accept other countries' trials, you do your own trials.

Dr. KESSLER. We do not do any trials ourselves, and over the last five years, I think if we go back and look at the record, we will find that we do accept foreign data.

Now, the issue you may be referring to, and I think we need to clarify it because I may be misunderstanding your question, RU-486 for cancer treatment, RU-486 as an abortive drug, the same drug.

But again, if we were to approve it, depending on what the indications are, you would have to have trials for cancer or trials as an abortifacient, so those are separate data.

BUYOUT

Mr. MYERS. One last question, and I apologize for taking the time, we have been working on the so-called buyout to reduce the number of Federal employees by 252,000 sometime over the next six years.

We're going to, well, we went to conference with the Senate yesterday and we are going back at 2:00 o'clock again today, what impact is that going to have on your agency?

Mr. WILLIAMS. In general, for the Department the buyout would be a significant element in our ability to meet the streamlining targets which we are committed to.

In the specific case of FDA, I don't know the specific data, but in general, we believe it's an important element to try to meet the streamlining goals that we've set for ourselves.

Mr. MYERS. But every year you come before this committee and say you don't have enough FTEs, and we sympathize with you and have tried to help you. How is this going to help you?

I support the buyout program, but I don't think it should be applied to every agency, and you are one of them that I have been battling I don't think should be applied to you, but I'm not in the executive either, so I don't know how that exactly will be applied. That's what I'm trying to find out.

Mr. WILLIAMS. And the Secretary has not applied the streamlining goals for the Department in an absolutely mathematical way either. She has made difficult priority decisions on the allocation of staffing and resources, and in the case of the Food and Drug Administration, with the help of the Chairman of this subcommittee and others, we were successful in getting a waiver from FTE reductions for the FDA, to enable it to move forward with its implementation of the Prescription Drug User Fee Act.

The Social Security Administration is another part of the Department that was granted a waiver for FTEs in order to handle the disability situation.

Mr. MYERS. Have you had to implement any RIF?

Mr. WILLIAMS. No, not at this stage, we have not, but the buyout would be useful to prevent the need for furloughs or other activities in our judgment.

Dr. KESSLER. Congressman, we all face challenges in the 1995 budget so that the tools to manage in very difficult economic times I think are important.

Mr. MYERS. I think someplace you are expecting 396, was it, FTE additions? Is that, did I read that in your testimony? It was 300- and some.

Dr. KESSLER. I think it's—

Mr. MYERS. Well, whatever it was, that's an increase and I think—it's 319, I see 319.

Dr. KESSLER. Again, the numbers are complex.

Mr. MYERS. Okay. Well, you might for the record, you have been given no guidelines I presume of what your discussion is here at this point, as to how you will have to implement, if you do, to comply with this buyout program.

Mr. WILLIAMS. Guidelines in what sense?

Mr. MYERS. Well, guidelines as to—are you going to be part of the reduction?

Mr. WILLIAMS. I think the Department intends that if the buyout authority is made available, that the Department would use that authority, to—

Mr. MYERS. Under the statute, both the Senate and the House, it is permanent, you can't get in this year and out next year. Once you reduce that slot, you can't fill it.

Mr. WILLIAMS. I understand.

Mr. MYERS. Seriously, I don't know how it could be applied to you folks—border patrol, FBI, Food and Drug Administration I think would be hit real hard.

Mr. WILLIAMS. Let me make a distinction between the Department of Health and Human Services and the specific case of the Food and Drug Administration. I'm not trying to speak—

Mr. MYERS. Well, I meant for the—

Mr. WILLIAMS. Okay, I'm sorry. I'm not trying to speak for the commissioner.

Dr. KESSLER. I apologize. Mr. Williams is the Deputy Assistant Secretary for Budget in the Department. If we could submit that for the record—

Mr. MYERS. If you would. We are going to make a decision in the next 24 hours on it though. That's what bothers me. Okay, if you don't have an answer, you don't. Okay.

[The information follows:]

FDA realizes that buyouts may be essential for a number of Federal agencies. Costs associated with buyouts may limit their usefulness to FDA in the context of the President's Budget. To achieve the personnel and related cost savings proposed in the FY 1995 President's Budget request for FDA, we may well need to utilize a variety of management tools. We might consider selective use of proposed "buyout" authorities, where cost and mission effective, assuming buyouts would not cause FTE reductions below the proposed FY 1995 President's Budget.

GENERAL USER FEE AUTHORITY

Mr. MYERS. Your budget request contains a proposal to collect user fees in 1995. There has been some discussion centering on the fact that some Federal agencies can collect user fees through the regulatory process rather than wait for a direct act of Congress. Do you believe you now have sufficient authority to collect user fees? If not, would Congressional action to impose user fees require an amendment to the Federal Food, Drug, and Cosmetic Act?

Dr. KESSLER. It is possible that in some cases user fees could be implemented by FDA under the general authority of 31 USC 9701,

often referred to as the general user fee authority. In other cases, the programs for which we might propose user fees might not meet the criteria of that authority, and might necessitate new statutory authority.

Mr. MYERS. Do you agree that any user fees collected from industry should be used specifically for speeding the FDA approval process?

Dr. KESSLER. The President's budget proposes new additive user fees for medical devices, a continuation of additive user fees for the drug and biologic review process, as well as \$228 million in new user fees to maintain current FDA activities.

Mr. DURBIN. Mr. Peterson?

Mr. MYERS. It's a very serious problem in our country. I have some other questions that I will provide for the record.

Mr. DURBIN. Mr. Peterson.

Mr. PETERSON. Thank you, Mr. Chairman. I will be brief and we will try to get you all out of here by 12:00 o'clock. I think that would make everyone happy.

Mr. MYERS. I'm sorry, I thought you had had your turn to ask questions.

TAXOL

Mr. PETERSON. I did, but just half of one. I want to commend the work on the mammography and Dr. Houn. This is something that is so key. This business of breast cancer is just devastating not only to individuals, but to the entire Nation, and this early detection is so very important, and whatever break-throughs that we're making there, we clearly have to make sure that what we're doing is right.

And by the certification process, that is certainly the first step.

But on another thing that we talked about last year, Taxol, I believe, we haven't talked to that at all. Is there any development there in synthetics or did we find more trees or, is there anything there that you know about?

Dr. KESSLER. On Taxol?

Mr. PETERSON. Yes, that would indicate adequate supplies that were cheap enough to where we could actually use it as a treatment?

Dr. KESSLER. There have been some major advances in the synthetic, so that we don't have to use the Pacific Yew tree.

Taxol is not the one where the real shortage is. We are facing these difficulties, for example, with betaseron, so it's not only things from the natural sources, but also biotechnology products.

What we're finding, and I think it's important for the Committee to understand, is that some of the drugs that we are reviewing and approving from the new biotechnology are complex to manufacture.

And if you in fact look at both the two drugs that I mentioned, DNase and betaseron, complex manufacturing issues become even more complex than the synthetic active ingredient in Taxol.

In fact, with betaseron, people have read, and I think some people are aware that there actually had to be a lottery. I read a story—it's interesting—that actually blamed the Agency for approving the drug too quickly, I mean, before there was enough.

You know, normally we get the comments that it takes us too long. Here we approved the drug, the center for biologics approved the drug so rapidly that the manufacturer—not to take away from the company's part, because it is very complicated to make the drug—just didn't have enough drug.

So I think it's not just Taxol. We are going to see these kinds of manufacturing issues for a range of products.

Mr. PETERSON. Let me go back.

Dr. KESSLER. Taxol, I mean—I need to clarify—it is now being produced from a semi-synthetic group.

Mr. PETERSON. A synthetic.

Dr. KESSLER. Yes.

USER FEES

Mr. PETERSON. Let me go back to one of the questions I asked earlier on the user fees, that \$228 million that you are going to get from unnamed user fees. Would you list for the record where you think those monies are going to come from?

Dr. KESSLER. Again, it's a very complicated issue, and we are working on that. I'm just not prepared at this point to—

Mr. PETERSON. I know. To reduce the complication, if you can just give us something for the record that we can see.

Dr. KESSLER. We would be happy to.

[The information follows:]

Because of the complexities involved, we are looking at virtually all FDA activities except those covered by specific current or proposed user fee authority. That leaves the food and animal drug activities of the agency, our activities at the National Center for Toxicological Research, generic and over-the-counter drug programs, blood banks, and most of our import and domestic inspection activities, and our enforcement and compliance activities.

IMPORT INFORMATION SYSTEM

Mr. PETERSON. All right. Last year we talked about a computer system that was going to allow us to detect border violations, and then those violation would be noted elsewhere.

Clearly that hasn't happened. In fact, as I understand it, 33 percent of the violations occur from just a very few vendors, and you're not really able to get the grips on that. Clearly the computer system would address that.

I haven't seen, unless I missed it, the numbers here for the computer system in your request.

Dr. KESSLER. Let me start. There is some good news or at least some interim progress on the Customs system. Let me let Dr. Henney start in and then Ms. Veverka can add on the systems question.

Dr. HENNEY. I believe it was last September, that we did a pilot test of our system out in Seattle. That was a very successful pilot. We have since put into place a similar kind of training for brokers and the like along the East Coast.

Those training sessions are going on right now, and we still have many things to work out with Customs, but we believe we're making considerable progress in that area.

Mr. PETERSON. Do you anticipate a time line for getting that whole system on-board and up and running?

Dr. HENNEY. I think Mary Jo would know exactly.

Ms. VEVERKA. As Dr. Henney indicated, we piloted the interface which just allows the broker to come in and enter the data electronically, and it goes through first an electronic screen against criteria that we've defined. That was piloted about a year and a half ago.

We are now rolling it out across the country. Over the next calendar year, it will be implemented in 18 sites across the country. That's the next phase of the project, but all that accomplishes is allowing the brokerage community to enter the data electronically, and have it first screened.

If it doesn't pass that screen, we still have to have the paperwork come in and take it through our normal inspection process. We're working on extending the system to provide more support to our management within the Agency but you are right, we still have to work out exactly what that's going to cost, and how we're going to fund those continued systems developments.

Mr. PETERSON. Okay, for the record, can you give us the 18 sites?

Ms. VEVERKA. Yes.

[The information follows:]

The 18 expansion sites and the expected on-line date for each are as follows:

Savannah, GA—March 14, 1994.
 Miami, FL—March 28, 1994.
 San Francisco, CA—April 11, 1994.
 Philadelphia, PA—April 25, 1994.
 New York, NY—May 23, 1994.
 Boston, MA—June 6, 1994.
 Buffalo, NY—June 20, 1994.
 San Diego, CA—July 11, 1994.
 Nogales, AZ—July 25, 1994.
 Los Angeles, CA—August 22, 1994.
 Memphis, TN—September 5, 1994.
 Chicago, IL—September 19, 1994.
 Cleveland, OH—October 3, 1994.
 Champlain, NY—October 17, 1994.
 Detroit, MI—October 31, 1994.
 Laredo, TX—November 14, 1994.
 El Paso, TX—November 28, 1994.
 Dallas, TX—December 12, 1994.

FOOD SAFETY

Mr. PETERSON. And talking about inspection, in re-inventing government, the Vice President has suggested that you would take over some USDA responsibility on the food and safety inspection process.

Is there anything moving within FDA to assume those duties, or any negotiations or even consideration for that?

Dr. KESSLER. We are working very closely with the U.S. Department of Agriculture on a whole number of fronts, and I think the first part of the Vice President's goal was to strengthen the Administration's presence in food safety.

We did that, I think considerably, by taking steps in the seafood program just a little while ago.

Mr. PETERSON. Let me interrupt there, because the seafood program has some inspection done by the Commerce Department?

Dr. KESSLER. That was a voluntary program, Congressman. The rules that we proposed would be a full, very comprehensive series of preventive controls that would have FDA oversight.

Mr. PETERSON. And would remove the other mechanisms.

Dr. KESSLER. It would still allow voluntary accreditation on other issues, but it would require mandatory compliance with a very extensive set of modern-day food safety principles.

Mr. PETERSON. Because of the vote and time, I yield back, Mr. Chairman.

Mr. DURBIN. Thank you very much.

Mr. PETERSON. Thank you very much.

LABORATORY FACILITIES

Mr. DURBIN. Dr. Kessler, let me say that there is a line of questioning which we will not have time to pursue, and I would like to ask if we can find a convenient time, that you might be able to return with some of your people.

It relates to investigation by the Committee which has determined that there are some problems with your laboratories. In fact, they have found only two of the 18 field laboratories of FDA are considered by your own agency to be modern, state-of-the-art facilities.

We've talked a lot about the responsibility of this agency, but I think those laboratories are the front line in terms of a lot of these responsibilities.

Dr. KESSLER. Those were the laboratories, for example, with the syringes in the Diet Pepsi.

Mr. DURBIN. Absolutely, and we have got to sit down with you in a separate meeting, I hope, and figure out how we are going to improve this, and do it in a systematic way.

And secondly, some questions have been raised about headquarters consolidation in this morning's paper, questions about cost of real estate and the projected cost of this consolidation having increased rather dramatically.

I would like to save that for a separate meeting where we could get into it in a little more detail.

Dr. KESSLER. We would be pleased.

Mr. DURBIN. If that is fine with you.

Let me say before I close here, Dr. Henney, we're going to miss you. She's going to New Mexico so Joe Skeen gets to do business with her a little more there.

Mr. MYERS. What's he got that we haven't got? [Laughter.]

Mr. DURBIN. I tell you, she is the kind of person we are lucky to have in the Federal Government.

Dr. HENNEY. Thank you.

Mr. DURBIN. And I thank you for your contribution. You have been great. Some of our colleagues, Ms. DeLuro, Ms. Vucanovich, Mr. McDade and Ms. Roukema, have some questions they would like answered for the record.

I would just like to close with a brief statement. The skeptics and the cynics and the ditto-heads who mock the importance of government in our lives should have been here today to see the Food and Drug Administration which spends less than one percent of our national budget, an agency with dedicated professionals who deal

with life and death issues everyday to protect our families, and help us live longer and better lives.

Keep up your good work. We're going to try to help you do an even better job.

Thanks, Doctor.

Dr. KESSLER. Thanks, Mr. Chairman.

MAMMOGRAPHY INSPECTION COSTS

Ms. DELAURO. In your justifications for fiscal year 1995, you say that you will provide such sums as may be necessary for the inspection of mammography facilities, "notwithstanding section 354(r) of the Public Health Service Act." As I read it, this section regards fees that the FDA is directed to collect to cover the cost of inspections, and that the amount of fees collected in any given year must equal the costs of inspections for that year. What is your specific intention with regard to section 354(r)?

RESPONSE. Section 354(r) of the Public Health Service Act requires that the costs of all inspections under the Mammography Quality Standards Act, for which charges are permitted, be paid from fees collected under that Act. The waiver requested in the appropriations act would allow FDA to pay for the costs of these inspections with appropriated funds in 1995, rather than from fees collected. The purpose is to allow FDA to capitalize this fund in 1995 with receipts collected, so there will be funds available in 1996 to begin paying these costs.

MAMMOGRAPHY QUALITY STANDARDS ACT

Ms. DELAURO. What proportion of the FDA staff people assigned to help implement the Mammography Quality Standards Act are trained in radiological health matters?

RESPONSE. Over 80 percent of the staff of the Division of Mammography Quality and Radiation Programs has training in radiological health matters. The remaining 20 percent of the personnel include: secretarial support staff, computer support staff, and consumer outreach staff. The division's Inspector Training Branch and Radiation Programs Branch began training the MQSA inspectors on January 24, 1994. These branches draw upon their considerable experience of training state and FDA inspectors through the Nationwide Evaluation of X-Ray Trends training program, a cooperative program between FDA and the States, the FDA X-ray Compliance course, and other courses FDA has collaborated in training state inspectors in mammography quality control.

Ms. DELAURO. Are these sufficient to train the State personnel needed to properly implement the Act and provide for adequate inspection of radiation producing machines used in mammograms?

RESPONSE. Because FDA now estimates the number of mammography facilities to be 14,255, we have made adjustments in meeting the demand for training more inspectors by seeking contractual agreements with private enterprises to assist in training.

Ms. DELAURO. During your negotiations with the States so far, what feedback have you received from them about your attempts to establish an effective facility inspection program?

RESPONSE. We have been in continuous contact with States about the establishment of an effective inspection program through several mechanisms. These include: conference between FDA and all States in January, 1994 to exchange ideas on MQSA implementation; input through the Conference of Radiation Control Program Directors; communication between the FDA Regional Radiological Health Representatives; and direct input by States during an inspection work session on March 15-16, 1994. Feedback on the program has been positive as we actively incorporate lessons from the State's mammography inspection experiences.

ORPHAN DRUG PROBLEM

Ms. DELAURO. There are more than 5,000 rare disorders. The scientists studying treatments for these illnesses depend almost solely on the FDA's orphan drug program for grants to study these disorders. How many grant applications has the FDA received each year under the Orphan Drug Program during the last 10 years? How many grants have been funded each year?

RESPONSE. I will be happy to provide this information for the record.

[The information follows:]

ORPHAN PRODUCT GRANT APPLICATIONS

Year	Applications received	Grants awarded
1983	56	8
1984	55	11
1985	46	21
1986	61	21
1987	47	23
1988	77	20
1989	115	21
1990	101	28
1991	19	29
1992	93	20
1993	57	20

¹ No general "Request for Applications" was published during this fiscal year. Applications funded in fiscal year 1991 were received and reviewed in the previous year.

Ms. DELAURO. There is some concern about the amount of funds required to administer the orphan drug grants program. Can you supply me with a detailed accounting of the administrative expenses incurred in overseeing this program?

RESPONSE. Grant applications received as a result of the annual Request for Applications are reviewed by ad hoc review panels comprised of experts in the field of the proposed studies. The panels are comprised of individuals from throughout the United States. During FY 1994, the office will hold 15 ad hoc review panel meetings involving the participation of approximately 75 expert reviewers. The estimated cost for these panel meetings is \$40,000.

Following panel meetings, the approved grants are reviewed according to routine government procedure by a second level council review. There are three council meetings a year. Two are usually held at the National Institute of Environmental Health Sciences in North Carolina and the other meeting is held on the NIH campus. The estimated cost for attendance of staff from the Office of Product Development at these meetings is \$3,600.

Approved grants are site visited by OPD staff, project officers, so that the FDA is assured the grant may lead to the development and potential approval of the FDA regulated product for a rare disease. Ideally grants would be site visited annually. This is not possible. Annually OPD is able to site visit approximately 25 studies. The projected cost for site visits in FY 1994 is \$30,000.

The total dollars incurred, then, for administration of the OPD grants program is \$73,600.

GENE THERAPY

Ms. DELAURO. Is the FDA considering creating a way to track gene therapy patients in order to assess the long-term affects of that therapy?

RESPONSE. FDA's Center for Biologics Evaluations and Research has been considering the possibility of developing a register of patients who are undergoing, or have recently undergone, gene therapy. The goal of this project is to establish a register that would provide users—primarily the FDA, the Center for Communicable Diseases, and the National Institutes of Health—with the ability to readily track adverse events of gene therapy, to note trends in therapeutic approaches and to possibly avert future adverse events.

A long-term goal of the program would be to grant the end user of the registry the ability to confirm that certain adverse effects from gene therapy do or do not occur, as well as the ability to determine whether certain adverse events related to gene therapy are hereditary. This program is innovative in that it could be accessible for end use by several distinct entities; the government, the public, industry, and Congress. Such a registration system would probably also have other potential benefits, not all of which are obvious at this time.

This project is in its early planning stage, with a number of meetings/workshops required to develop a consensus about the design and development of the registry. Until some basic questions are answered, such as: what specific variables should be captured; who should collect, maintain, analyze, and disseminate the data and under what procedures; and, how can patient confidentiality be protected? Given the wide range of questions and differences of opinion expressed on them, the Center intends to vigorously pursue solutions to the many unresolved issues that still face a possible gene register program.

Ms. DELAURO. What would be the cost of establishing such a gene therapy registry?

RESPONSE. Until the information is developed and the extent of the efforts required to establish a national gene registry can be identified, we are unable to develop a reliable estimate of costs.

SCLERODERMA

Ms. DELAURO. I understand that the new systemic sclerosis controller clinical trial is up and running, and that the sponsor has filed a treatment IND to expand the uses of photopheresis in this life threatening disease. What is the status of FDA's review? Is it on clinical hold? If so, what are the reasons for the clinical hold, and what is being done to work with the sponsor to resolve the issues surrounding the clinical hold?

RESPONSE. The regulations governing treatment INDs are set forth at 21 CFR 312.34 and 312.35. FDA considers information about pending applications to be confidential commercial information and only publicly comments on a pending application when it is the subject of a public Advisory Committee meeting. Thus, FDA can neither confirm or deny the existence of a treatment IND nor comment on FDA's evaluation of any such document.

Ms. DELAURO. Given the clinical hold with the treatment IND, would the review of the results from the sponsors current ongoing clinical trial still qualify, as previously stated by you, under the accelerated review approval initiative?

RESPONSE. I have previously said that FDA would review an NDA for the use of methoxsalen/photopheresis for treatment of systemic sclerosis under the accelerated approval procedures. Systemic sclerosis is viewed as a serious disease, and advanced stages of the disease are life-threatening. This position remains unchanged.

Ms. DELAURO. It is my understanding that FDA inspection activities at the facility of the sponsor of these clinical trials have increased over the past year or two. Is this the case? What has the FDA found? What are the reasons for these ongoing inspection activities?

RESPONSE. Due to the confidential nature of the ongoing review, I cannot answer your questions at this time.

rBGH (BOVINE GROWTH HORMONE)

Ms. DELAURO. There are concerns that milk from rBGH-treated cattle may be a factor for breast cancer. Has the FDA thoroughly investigated these concerns? What, specifically, were your findings?

RESPONSE. FDA considered potential human safety concerns regarding the use of rBGH in dairy cows and concluded that consumption of milk and meat from treated cows is safe for consumers. There is absolutely no evidence that the consumption of milk from rBGH-treated cows increases the risk of breast cancer.

Ms. DELAURO. Professor Samuel Epstein has raised questions about the possible increase in IGF-1 due to rBGH, and the increased risk of breast cancer associated with heightened levels of IGF-1. He argues that IGF-1 is not destroyed by pasteurization; and is not affected by human digestion. He also points out that an FDA publication showed that oral administration of small doses of IGF-1 caused significant effects on laboratory rats. Yet the FDA has found that IGF is not harmful when taken orally.

Has the FDA studied the connection between IGF-1 and rBGH? Does rBGH increase IGF-1?

RESPONSE. IGF-I is a natural protein required for normal growth and, possibly, health maintenance. It is structurally and chemically similar to insulin and is normally present in almost all human body tissues and fluids including human breast milk and saliva. The consumption of dietary IGF-I plays no role in either inducing or promoting any human disease, nor does it cause malignant transformations of normal human breast cells.

Abnormally low levels of IGF-I in humans are associated with several disease conditions including dwarfism, malnutrition, osteoporosis, and infertility. It has been suggested that a decline in IGF-I levels in human tissue causes many of the degenerative changes associated with aging.

Levels of IGF-I in cows' milk and meat are much lower than levels found naturally in human blood and other body tissues. Treatment of dairy cows with rBGH does not increase the levels of IGF-I in their milk above the levels normally found in milk of non-treated animals.

It is true that IGF-I is not destroyed by pasteurization. However, IGF-I is not absorbed intact. Similar to other proteins such as insulin, dietary IGF-I in milk and meat is broken down in the gastrointestinal tract by digestion. In studies, oral ad-

ministration of large doses—up to 2000 mg/kg/day—of IGF-I to rats did not cause significant toxicologic effects on the animals. I will provide for the record information on other studies that support these findings.

[The information follows:]

For further reference, see Terrill, 1989, results of study HLA 241-219 submitted to WHO by Monsanto Agricultural Company, St. Louis, MO; Fisher and Russell, 1988, results of studies D03888 and D05980, submitted to WHO by Elanco Regulatory Services, Indianapolis, IN; see attached reference: "Toxicological evaluation of certain veterinary drug residues in food," WHO Food Additives Series: 31, 1993.

IGF-I AND BREAST CANCER

Ms. DELAURO. Is IGF-I correlated to breast cancer? Can you substantiate this answer? If not, should further studies regarding this potential link be carried out?

RESPONSE. FDA evaluated the effect of rBGH treatment of dairy cows on IGF-I in milk and meat of the treated animals and concluded that there was no increased human food safety concern. Studies revealed that treatment of cows with rBGH increases IGF-I levels in their plasma but does not increase milk IGF-I levels above the values found naturally in milk. IGF-I is normally present in nearly all human body tissues and fluids. Levels of IGF-I in cows' milk and meat are much lower than levels found naturally in human blood and other body tissues. Levels of IGF-I in human milk are similar to the levels found in cows' milk.

A link between IGF-I and breast cancer has been speculated in the scientific literature, but only in the sense that IGF-I promotes the growth of all cells, cancerous and normal, under the strictly defined conditions involved in scientific experimentation. The same effect is noted for insulin and other proteins found in the human body. However, there is no evidence that IGF-I causes breast cancer or is responsible for malignant transformation or metastasis of breast cancer cells. Furthermore, dietary IGF-I has no role in breast cancer because it is broken down during digestion.

Thus, with respect to the human safety of rBGH use in dairy cows, FDA has concluded that no further studies need to be conducted.

rBGH AND HUMAN HEALTH

Ms. DELAURO. Professor Epstein argues that the conclusions about the potential impact on human health are based upon a single, unpublished, report prepared by J.B. Terrill of Hazelton Laboratories of America Inc., at the request of the manufacturer of rBGH. Professor Epstein has argued that the research was faulty and that its conclusions were "gerrymandered."

In light of the fact that this report is central to concerns about the impact on human health of rBGH, would FDA make this report available to this committee?

RESPONSE. FDA's conclusions on the human safety of rBGH are based upon the results of hundreds of studies, not a single experiment. These studies evaluated such topics as protein digestion, effects of the treatment of humans with pituitary BGH, levels of IGF-I in milk and meat of rBGH-treated and untreated cows, and the physiological effects of IGF-I.

The majority of these studies are reported in the peer-reviewed scientific literature. Results of many of these studies are summarized in reviews such as *Science*, Volume 249, pages 875-884, 1990, and more recently reported by the World Health Organization in WHO Food Additives Series: 31, "Toxicological evaluation of certain veterinary drug residues in food," 1993; and FAO Food and Nutrition Paper: 41/5, "Residues of some veterinary drugs in animals and foods," 1993.

In cases where data required by FDA to make decisions are not available in the scientific literature, the drug sponsor is responsible for providing the data. The drug sponsor may conduct the study or may have the research performed by a contract laboratory. FDA monitors the quality control of studies submitted from drug sponsors through several means, e.g., the Good Laboratory Practices regulations, on-site inspections of the study facilities by FDA investigators and scientists, and the requirement that all raw data be submitted to FDA.

Data submitted to FDA from drug sponsors are considered proprietary and cannot be released unless they are already available to the public or permission is granted by the sponsor for their release. I will be happy to provide the information to the Committee under separate cover.

Ms. DELAURO. What studies have been done to assess the effects of rBGH on humans? Could you please provide a list of those studies?

RESPONSE. A number of studies on the effects of rBGH on humans have been reported in the peer-reviewed scientific literature. Results of many of these studies are summarized in reviews such as *Science*, Volume 249, pages 875-884, 1990, and

more recently reported by the World Health Organization in WHO Food Additives Series: 31, "Toxicological evaluation of certain veterinary drug residues in food," 1993; and FAO Food and Nutrition Paper: 41/5, "Residues of some veterinary drugs in animals and foods," 1993. I will be happy to provide copies of *Science* and the World Health Organization article for the record.

[CLERK'S NOTE.—Reports have been provided to the Committee but have not been included because of their volume.]

RBGH MILK AND BREAST CANCER

Ms. DELAURO. Have any studies been done, to your knowledge, on the possible links between drinking rBGH milk and breast cancer?

RESPONSE. Hundreds of studies have contributed to FDA's conclusion that the use of rBGH in dairy cows poses no human safety concerns. The concerns about rBGH and breast cancer are unfounded based upon the following facts: IGF-I is a natural protein required for normal growth and possibly health maintenance and is normally present in almost all human body tissues and fluids; levels of IGF-I in cows' milk and meat are much lower than levels found naturally in human blood and other body tissues; treatment of dairy cows with rBGH does not increase the levels of IGF-I in their milk above the levels normally found in milk of non-treated animals; similar to other proteins, dietary IGF-I is broken down in the gastrointestinal tract by digestion; and there is no evidence that IGF-I causes breast cancer or is responsible for malignant transformation or metastasis of breast cancer cells.

Ms. DELAURO. Do the myriad health complications caused in cows by rBGH, and mentioned on the label for Posilac[™], Monsanto's brand name for rBGH, cause you any pause in certifying this product as safe for people?

RESPONSE. As with any other drug approved by the FDA, cautions and warnings are listed on the product labeling to alert users of Posilac[™] to potential side effects that may occur in treated dairy cows. FDA considered potential human safety concerns regarding the use of rBGH in dairy cows, including the side effects that may occur in treated animals, and concluded that consumption of milk from treated cows is safe for consumers.

MAMMOGRAPHY

Ms. VUCANOVICH. I appreciate the work the FDA has completed to ensure that mammography is safe and reliable. As you know, the State of Nevada is one of the few States to have implemented State sanctioned mammography guidelines which I shared with the Food and Drug Administration last year. When developing your regulations for mammography quality, did you contact State officials in Nevada and how similar are the regulations to the state regulations?

RESPONSE. FDA obtained State input into regulation development through the Conference of Radiation Control Program Directors. FDA also borrowed from the regulations and programs of several States, including Nevada, when developing the quality standards. The regulations are similar to Nevada's regulations, but exceed them by requiring all facilities to undergo clinical image review to ensure image quality.

Ms. VUCANOVICH. Will the State of Nevada, or other States which have similar State guidelines, be forced to make many changes under the FDA's guidelines?

RESPONSE. States are allowed to have stricter regulations under MQSA, but in States with no mammography regulations, or with lax ones, all facilities must meet the national quality standards.

MAMMOGRAPHY QUALITY STANDARDS ACT

Ms. VUCANOVICH. Do you believe you will be on time to fully certify and inspect all mammography facilities?

RESPONSE. FDA is proceeding with deliberate speed to certify all accredited mammography facilities and is proceeding with plans to inspect all mammography facilities.

Certification is dependent on a facility first becoming accredited by a body approved by the FDA. At this time only two entities have applied to be accrediting bodies: the American College of Radiology and the State of Iowa. Once approved, FDA will ask these groups for their plan for accrediting all applicants prior to October 1, 1994.

Ms. VUCANOVICH. Last year, the assignment of FTEs to this program was a problem. Under the budget proposal, do you believe that you will have enough FTEs assigned to this task this year?

RESPONSE. The FY 1995 budget provides an additional 31 FTEs for a total of 61 FTEs, the staffing level needed to implement MQSA.

Ms. VUCANOVICH. As you know, the National Cancer Institute recently changed its recommendation guidelines for mammography screening for women. Many argue that these studies used to base their new recommendations were faulty and simply outdated—in fact, mammography quality of thirty years ago may have led to erroneous data. In trying to develop new standards, I am certain that the FDA learned a great deal about mammography quality in past years. Did the National Cancer Institute confer with you about mammography quality before changing their guidelines and would you care to comment on the effect of mammography quality on past breast cancer studies?

RESPONSE. The National Cancer Institute did not confer with FDA about mammography quality before changing their guidelines for mammography screening. FDA has learned a lot about mammography quality over the years. However, because only one previous screening mammography study has published information on mammography quality, FDA is unable to comment on the overall effect of mammography quality on past breast cancer studies.

SILICONE BREAST IMPLANTS

Ms. VUCANOVICH. Several years ago, the FDA took corrective action on silicone breast implants and determined to study these implants. Please tell me the status of these studies?

RESPONSE. The Internal Public Health Service Breast Task Force on Silicone Breast Implants was established in March 1992 by the U.S. Department of Health and Human Services. This task force developed a plan for further research relating to these devices that included the initiation of silicone breast implant clinical studies that were scheduled in three overlapping stages: Stage I, Urgent Need Exemption; Stage II, Adjunct Clinical Protocol; and Stage III, Core Clinical Protocol.

Currently, there is only one company participating in clinical trial protocols with the silicone breast implant devices; the subject enrollment for the adjunct stage thus far is 7,000 patients, with a total of 11,239 devices having been implanted. To date, the Core Clinical Protocol for these devices has not been implemented.

Ms. VUCANOVICH. I have been told that other materials, besides silicone, have been brought to the FDA for approval. Could you briefly share some of these proposals and the position of the FDA on these materials used in breast implants?

RESPONSE. Other materials brought to the FDA for approval includes saline-filled breast implant devices. In addition to these devices, one company has gone public with an IDE submission to the Agency for use of a radiolucent oil as an alternative. The submission is currently undergoing review. FDA recognizes the urgent public health need for alternatives to silicone and has developed a draft guidance for these devices.

Ms. VUCANOVICH. It is my understanding that the use of silicone in other medical devices has caused worry for the FDA. Is this an ongoing problem or is the FDA continuing to study this problem?

RESPONSE. In order to clarify the situation, I should mention that the silicone breast implant issue was specifically concerned with the use of silicone *gel* and the release of this material within the body. Another issue is the use of silicone *elastomers* in medical devices generally. Silicone gel and silicone elastomers are two entirely different substances. The main concern regarding devices that contain silicon is the recent withdrawal of silastic materials from the market by Dow Corning. The Agency is concerned with the impact of this event on the silicone devices that are currently being marketed. Therefore, the Agency has announced the availability of a guidance document entitled, "Strategy for Management of Devices Affected by the Withdrawal of Dow Corning Implant Grade Silicone materials," which describes the procedures to be followed by manufacturers in determining when to make a submission pursuant to an alternative review process. I will provide a copy of this guidance for the record.

[The information follows:]

STRATEGY FOR MANAGEMENT OF DEVICES AFFECTED BY THE WITHDRAWAL OF DOW CORNING IMPLANT GRADE SILICONE MATERIALS

Background: Dow Corning currently markets 50 silicone oil and elastomer materials. Five of these materials are described by Dow Corning as "Implant Grade" materials, i.e. Dow Corning has up to 2 years of animal implantation data on them.

Dow Corning will withdraw these materials from the market, effective 31 March 1993. In addition, they will deny access to the DMF for these materials effective immediately. The company's position to continued sale of silicone oils and other grades of elastomers is not affected by this decision.

FDA staff has evaluated the impact of this decision by Dow Corning and is concerned about the continued availability of devices manufactured from silicone elastomer.

Dow Corning Products Affected: The following "Implant Grade" silicone elastomers will be withdrawn:

MDX4-4515: Peroxide Cured 50D Elastomer.

MDX4-4516: Peroxide Cured 60D Elastomer.

Q7-2245: Platinum Cured 40D Elastomer.

Q7-2213: Dispersion in Chlorothen.

HP Tubing.

STRATEGY

1. FDA/CDRH will work with the medical device industry to develop a complete characterization for implant polymer materials and get this credentialed, e.g., approved as an ASTM Standard.

2. FDA/CDRH will work with the industry to identify a set of chemical, physical and biological characteristics which will allow us to define that a silicone elastomer manufactured by a firm other than Dow Corning is not different from the Dow Corning elastomer.

3. Based on the anticipated public health impact, FDA will consider establishment of a "Materials Shortage" status for the materials affected by this corporate decision to withdraw from major sectors of the industry.

4. FDA will require the holders of currently approved PMAs and 510 (k)s to document in a new submission that the material they use in their manufacture of a medical device is "not substantially different" from the materials they have described in their application, as defined by the above set of characterization tests.

WOMEN IN CLINICAL TRIALS

Ms. VUCANOVICH. I am pleased to hear that the FDA is working to include women in clinical trials. Could you provide more information on these trials and how you will implement the guidelines.

RESPONSE. A Guideline for the Study and Evaluation of Gender Differences for the Clinical Evaluation of Drugs was published by the Agency on July 22, 1993. This guideline calls for better assessment of possible gender differences in response to new medications, and specifically encourages companies to include patients of both sexes in drug development trials, something which they have, in general done in the past. Additionally, they are also to analyze the effectiveness and safety for significant differences in response between men and women, directing particular attention to possible pharmacokinetic effects associated with the phases of the menstrual period, menopause and use of oral contraceptives or estrogens. In this way, the guideline will help ensure that the safety and efficacy of drugs are adequately studied in the full range of patients who will receive therapy upon approval.

FDA reviewers have been asked to ensure that demographic analyses are performed pursuant to the guideline. Where such analyses are absent or inadequate, the FDA division may request that sponsors provide the appropriate analyses or, if warranted, may refuse to file the application. A letter was sent to the Pharmaceutical Manufacturers Association to convey this information to industry.

Ms. VUCANOVICH. Furthermore, could you go into more detail on the role of the Office of Women's Health and what you expect to see in the next five years.

RESPONSE. The Office of Women's Health is now being formalized in the Office of the Commissioner. On March 3, 1994, the Commissioner and the Senior Staff of the Agency met to discuss formation of this new office and to promote a cohesive approach in its mission.

The Office will work closely with the Commissioner, the Office of External Affairs, and the Centers within FDA to insure that regulatory and oversight functions of the agency are gender sensitive and responsive. It will work to correct gender disparities in drug, device and biologics testing and regulation policy, and will monitor the implementation of the revised clinical trial guidelines to ensure that women are adequately represented in clinical trials and that gender analyses are routinely included in product applications. In collaboration with appropriate Centers, the Office of Women's Health will also begin to address issues related to the testing of drugs and biologics in pregnant women.

In addition to issues of clinical trials, the Office will work closely with the Center for Devices and Radiologic Health on the implementation of the Mammography Quality Standards Act. Other issues that will be a priority for this office include encouraging development and approval of products for contraception and protection of women against sexually transmitted diseases including AIDS. Agency issues per-

taining to cancer in women, particularly breast cancer will also be a priority. The Office of Women's Health will serve as a focal point for issues related to breast implants—silicone gel, saline, and newer implants that may be developed—particularly as data is generated over the next five years.

The Office of Women's Health plans to establish an outreach strategy in order to obtain advice and recommendations on issues that should be addressed and on matters where broad input is required. The Office will form linkages internally and externally with groups that include scientists, health professionals, policy makers, and consumer organizations. Over the next five years, the Office intends to develop a clearinghouse system for tracking and coordinating women's health activities across FDA Centers and Offices; guidance documents on points to consider for approval of products to be used by women; and a database of drugs and other products that act differently in men and women.

DIETARY SUPPLEMENTS

Ms. VUCANOVICH. As you know, many people in the country, including my State of Nevada, believe that the right to take dietary supplements should not be taken away from them and should not be regulated. During the past few years, the FDA has inspected and searched many manufacturing plants, wholesaler and retail outlets of dietary supplements and herbal medicines. Of these facilities, how many and what products were confiscated? Could you provide a list of the locations of the facilities raided by the FDA and the products alleged to be in violation of FDA drug or label laws?

RESPONSE. FDA executed search warrants at a number of locations. Some of the drugs alleged to be in violation of the Food, Drug, and Cosmetic Act in the affidavits in support of the search warrants give the appearance of being dietary supplements because of their names. The drugs at issue were misbranded, unapproved new drugs, or in some cases smuggled into the country. These drugs, in most instances, made unsubstantiated claims for the cure or mitigation of serious disease conditions.

I will be happy to provide the information you requested for the record.

[The information follows:]

Search warrants executed 5/14/92:

For Your Health Pharmacy, Kent, Washington.

Tahoma Clinic and Meridian Valley Clinical Laboratory, Kent, Washington. [Drugs alleged to be in violation of the Act—injectable Magnesium-ATP, injectable Zinc, injectable selenium, DHEA capsules, Ditocarb Sodium, Centrophenoquine.]

Search warrants executed 6/24/93:

International Nutrition, Inc., Las Vegas, Nevada and—2550 Chandler Drive, Storage Locker #496.

Papillon Botanicals, Las Vegas, Nevada.

Ramona Manufacturing Co., Pahrump, Nevada.

Search warrant executed 8/3/93:

International Nutrition, Inc., El Paso, Texas. [Drugs alleged to be in violation of the Act—all making serious drug claims: Pau D'Arco, L-Carnithine with Magnesium Arginate, Cal-ORO-500, Calcium Aspartate, Membrane Complex, Calcium Arginate/Calcium Orotate, Magnesium Arginate/Magnesium Orotate, Lithium Arginate/Lithium Orotate, Potassium Arginate/Potassium Orotate, Zinc Arginate/Zinc Orotate, Calcium Aspartate, Potassium-Magnesium Aspartate, Carotavit, Selenium, E-Complex, GTF Chromium, L-Carnitine, Colamine-Phosphate Complex, Shark Cartilage, E-mag, Bromelain, L-Lysine, Carnivora, Nieperzyme.]

RECALLS OF DIETARY SUPPLEMENTS

FY 92—22 Recalls

Ferrous Sulfatedyna-Bor Plus, Liquid Protein, Various Dietary Supplements, Tri Vit Drops, Vitamin E Lotion, Bulk Supplement Tablets, and Flavorzest Oral Liquid.

FY 93—16 Recalls

Super Vitura 100 Supplement, Vitamin B-1, Uni-Daily plus Iron, Multi-vita Drops & Daily Vitamin Liquid, L. Carnitine, Pediatric Electrolyte, Vitamin B-6 Tablets, Kelp Natural Iodine Tabs, Calcium with Vitamin D Tablet, NCHF & Immusyn-C Nu Cell Herbal Formula, Nature Made Vitamin E, and Vitamin A Tablets.

FY 94 (6 Months)—2 Recalls

Ferrous Gluconate Tabs, and High Potency Multivitamin & Minerals w/ Betacarote.

DIETARY SUPPLEMENTS

Ms. VUCANOVICH. Also, how many people were taken ill or died from taking dietary supplements?

RESPONSE. During fiscal year 1992, FDA received 114 consumer complaints of illness/injury, the occurrence of symptoms, treatment by a physician or a hospital visit associated with the use of dietary supplements. Three complaints involved death. These were 163 consumer complaints in FY 1993 with no deaths and 94 complaints thru 5 months FY 1994 with no deaths.

Ms. VUCANOVICH. How many full time employees, temporary or part time employees are involved in the FDA's enforcement and regulation of the dietary supplement and herbal medicine industry?

RESPONSE. We do not have specific staffing data available because a unique tracing code for dietary supplement work was not incorporated into the workload tracking system until FY 1994. We estimate that in FY 1994 and FY 1995, 121 FTEs will be involved in dietary supplement activities.

These resource estimates are based primarily on a very labor-intensive manual review of the FY 1992 field work data files performed as part of a General Accounting Office study in 1993. The figures are based on a broad definition of dietary supplement work including all related activities in the foods and human drugs programs, and also includes resources expended on major criminal cases involving a combination of illegal drugs and dietary supplements products when no breakout between the two product groups could be done. The manual review included more than 80,000 FY 1992 computer records in determining what resources were expended on supplements work by field components in that year. This field data was combined with figures provided by Headquarters elements to arrive at a total estimated usage figure for FY 1992 of 121 FTEs. At this time, our best estimate is that work in this area continued at about the same rate in FY 1993 and will be performed at a similar level in FY 1994 and FY 1995.

Ms. VUCANOVICH. What is the total cost for FY 92 and FY 93 and estimated costs for FY 94 and FY 95 for FDA from appropriated dollars and user fees?

RESPONSE. Based on the workload estimates established in the GAO study, and assuming a consistent level of workload through the succeeding years, we estimate our costs at approximately \$9.6 million for FY 1992, \$10.2 million for FY 1993, and \$10.8 million for FY 1994 and FY 1995.

PRESCRIPTION DRUG USER FEES

Ms. VUCANOVICH. Could you please provide me with an update of the Prescription Drug User Fee Act including information on the number of FTEs you have hired? How many of the FTEs hired are product reviewers to speed up the drug approval process?

RESPONSE. The implementation of this new statute has been a very demanding undertaking. It defined many old processes in new ways, and demanded that we make substantial adjustments in how the Agency does business in order to accommodate the requirements of this Act. Regarding the recruiting goal set out in the letters, we are on target. We have about 180 more FTEs on board now dedicated to the process for the review of human drugs than we had in 1992, before the passage of the Act. We are continuing to recruit aggressively, and incremental our on-board staff dedicated to this process should exceed 350 by the end of this fiscal year. Most of these FTEs are in the biologics and drug product review and evaluation divisions.

Ms. VUCANOVICH. Do you have any results on how the review process has been affected?

RESPONSE. Backlogs of overdue original new drug applications were reduced from 35 to 6 in our Center for Drug Evaluation and Research, and from 9 to 3 in our Center for Biologics Evaluation and Research, as of January 31, 1994.

The real impact of increased review staff on review times will take a while to show, as it cannot be measured until applications submitted each year have been acted upon. It also takes time to train new staff before they are fully productive in their work. We do have every reason, however, to expect continued improvement consistent with the Prescription Drug User Fee Act goals.

OTHER USER FEES

Ms. VUCANOVICH. I notice the proposal to collect \$228 million from industries other than prescription drugs, medical devices and mammography. What industries would these fees be imposed upon?

RESPONSE. There are many complex issues associated with collecting substantial new user fees. I can assure you that we are looking at possible candidates for such fees. We are looking at virtually all FDA activities except those covered by specific current or proposed user fee authority.

Areas under consideration include the food and animal drug activities of the agency, our activities at the National Center for Toxicological Research, generic and over the counter drug programs, blood banks, and most of our import and domestic inspection activities, and our enforcement and compliance activities. One of the first items we looked at was our import activities. Because our plans have not been finalized, I am unable to advise you about how the fees will be levied on the regulated industry.

Ms. VUCANOVICH. What is the direct benefit to these industries in the FDA—for example, under the prescription drug user fees additional reviewers are to be added—how will these new industries benefit?

RESPONSE. In some of these areas there is a significant benefit to the industry—they are unable to enter their products into the marketplace without FDA approval of their applications. This applies to animal drugs, generic drugs, and food additives. In other areas the benefit may not be as directly identifiable, which may require separate statutory authorization for fees, rather than the authority of the Prescription Drug User Fee Act.

REGULATION OF TOBACCO

Mr. MCDADE. A recent February 26, 1994 article in the Los Angeles Times reported on "a major policy reversal", where "the FDA asserted its authority under existing law to regulate and even ban virtually all cigarettes". What is the specific legislative and regulatory authority which the Food and Drug Administration asserts its power to ban the growth, manufacture, and use of cigarettes or other tobacco projects. Please explain FDA Commissioner David A. Kessler's opinion cited in the LA Times article that "cigarettes, are in effect a drug that falls under FDA regulatory jurisdiction"?

RESPONSE. In a letter dated February 25, 1994, to the Chairman of the Coalition on Smoking Or Health, Dr. Kessler discussed FDA's current consideration of information regarding the regulatory status of cigarettes. The Coalition had petitioned the Agency to regulate low-tar and low-nicotine cigarettes and denicotinized cigarettes as drugs.

Dr. Kessler's letter discussed the definition of a "drug" under the Federal Food, Drug, and Cosmetic Act. Under this definition, products are subject to regulation as drugs based on the intent of the product vendor. Generally, there must be an intent that the product be used either in relation to a disease or to affect the structure or function of the body.

The letter states that evidence is accumulating that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers. This possible inference is based on mounting evidence that the nicotine in cigarettes is addictive and that cigarette vendors control the nicotine levels.

The letter states that the evidence suggests cigarette vendors intend that many people buy cigarettes to satisfy their nicotine addiction. The letter also states that if the Agency were to make this finding based on an appropriate record or be able to prove these facts in court, the Agency would have a legal basis on which to regulate the products as drugs. The letter does not state that the Agency has already reached the conclusion that cigarettes are drugs under the statutory definition.

Among the various provisions of the FD&C Act regarding drugs are sections 501—adulteration, 502—misbranding, 503—prescription drug limitations, and 505—pre-market approval of new drugs.

Dr. Kessler stated in the letter his desire to work with Congress to resolve the regulatory status of cigarettes.

DIETARY SUPPLEMENTS

Mr. MCDADE. During the past three fiscal years FY 1992, 1993, and 1994 how many manufacturing plants, wholesale and retail outlets of dietary supplements and herbal medicine has FDA inspected and subsequently received search warrant approvals to investigate? Of these facilities how many and what products were confiscated or recalled from the market?

RESPONSE. FDA executed search warrants at a number of locations. Some of the drugs alleged to be in violation of the Food, Drug, and Cosmetic Act in the affidavits in support of the search warrants give the appearance of being dietary supplements because of their names. The drugs at issue were misbranded, unapproved new

drugs, or in some cases smuggled into the country. Drugs in most instances made unsubstantiated claims for the cure or mitigation of serious disease conditions.

I will be happy to provide information on search and seizures and recalls for the record.

[The information follows:]

Search warrants executed 5/14/92:

For Your Health Pharmacy, Kent, Washington.

Tahoma Clinic and Meridian Valley Clinical Laboratory, Kent, Washington. [Drugs alleged to be in violation of the Act—injectable Magnesium-ATP, injectable Zinc, injectable selenium, DHEA capsules, Ditocarb Sodium, Centrophloxine.]

Search warrants executed 6/24/93:

International Nutrition, Inc., Las Vegas, Nevada and—2550 Chandler Drive, Storage Locker #496.

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Ramona Manufacturing Co., Pahrump, Nevada.

Search Warrant executed 8/3/93:

International Nutrition, Inc., El Paso, Texas. [Drugs alleged to be in violation of the Act—all making serious drug claims: Pau D'Arco, L-Carnithine with Magnesium Arginate, Cal-ORO-500, Calcium Aspartate, Membrane Complex, Calcium Arginate/Calcium Orotate, Magnesium Arginate/Magnesium Orotate, Lithium Arginate/Lithium Orotate, Potassium Arginate/Potassium Orotate, Zinc Arginate/Zinc Orotate, Calcium Aspartate, Potassium-Magnesium Aspartate, Carotavit, Selenium, E-Complex, GTF Chromium, L-Carnitine, Colamine-Phosphate Complex, Shark Cartilage, E-mag, Bromelain, L-Lysine, Carnivora, Nieperzyme.]

RECALLS OF DIETARY SUPPLEMENTS

FY 92—22 recalls

Ferrous Sulfatedyna-Bor Plus, Liquid Protein, Various Dietary Supplements, Tri Vit Drops, Vitamin E Lotion, Bulk Supplement Tablets, and Flavorzest Oral Liquid.

FY 93—16 recalls

Super Vitura 100 Supplement, Vitamin B-1, Uni-Daily plus Iron, Multi-vita Drops & Daily Vitamin Liquid, L. Carnitine, Pediatric Electrolyte, Vitamin B-6 Tablets, Kelp Natural Iodine Tabs, Calcium with Vitamin D Tablet, NCHF & Immusyn-C Nu Cell Herbal Formula, Nature Made Vitamin E, and Vitamin A Tablets.

FY 94 (6 Months)—2 recalls

Ferrous Gluconate Tabs, and High Potency Multivitamin & Minerals w/ Betacarote.

Mr. McDADE. How many criminal and or civil actions were taken, and what were the outcomes of these cases?

RESPONSE. In FY 1992, FDA recommends six seizures and six prosecutions. All six prosecution recommendations involved Gamma Hydroxy Butyrate, commonly referred to as GHB, a substance promoted as an alternative to steroids to a segment of the population that uses illegal steroids to build body muscles. GHB does not fit the definition of a dietary supplement, but the product is widely available through stores that sell dietary supplement products. All six seizures were successfully accomplished and none were contested. The prosecutions are in various stages of litigation.

In FY 1993, FDA recommended nine seizures and five prosecutions. Four of the prosecution recommendations were for GHB. The seizures were successfully executed, and the prosecutions are progressing. There were no recommendations in FY 1994 for either civil or criminal actions against dietary supplements.

Mr. McDADE. Provide a list of the locations of the facilities raided by FDA and the products alleged to be in violation of FDA drug or label laws or regulations?

RESPONSE. FDA does not conduct "raids." In co-operation with United States Attorney's offices, we do execute search and seizure warrants on firms that are believed to be in violation of the Food, Drug, and Cosmetic Act. Search warrants were executed at a number of locations. In some instances, drugs alleged in the affidavits supporting the search warrants to be in violation of the Food, Drug, and Cosmetic Act appear to be dietary supplements because of their names. However, these drugs were misbranded, unapproved new drugs, or in some cases, smuggled into the country. In most instances, the drugs made unsubstantiated claims for the cure or mitigation of serious disease conditions.

Mr. MCDADE. How many persons were made ill or died from taking dietary supplements of herbal medicines from these facilities?

RESPONSE. During fiscal year 1992, FDA received 114 consumer complaints of illness/injury, the occurrence of symptoms, treatment by a physician or a hospital visit associated with the use of dietary supplements. Three complaints involved death. There were 163 consumer complaints in FY 1993 with no deaths and 94 complaints thru 5 months FY 1994 with no deaths.

Mr. MCDADE. How many full time employees, temporary, or part time employees are involved in FDA's enforcement and regulation of the dietary supplement and herbal medicine industry and what is the total cost for FY 1992 and 1993 and estimated costs for FY 1994 and FY 1995 for FDA from appropriated dollars and from user fees?

RESPONSE. We do not have specific staffing data available because a unique tracking code for dietary supplement work was not incorporated into the workload tracking system until FY 1994. We estimate that in FY 1994 and FY 1995, 121 FTEs will be involved in dietary supplement activities.

These resource estimates are based primarily on a very labor-intensive manual review of the FY 1992 field work data files performed as part of a General Accounting Office study in 1993. The figures are based on a broad definition of dietary supplement work including all related activities in the foods and human drugs programs, and also includes resources expended on major criminal cases involving a combination of illegal drugs and dietary supplements products when no breakout between the two product groups could be done. The manual review included more than 80,000 FY 1992 computer records in determining what resources were expended on supplements work by field components in that year. This field data was combined with figures provided by Headquarters elements to arrive at a total estimated usage figure for FY 1992 of 121 FTE. At this time, our best estimate is that work in this area continued at about the same rate in FY 1993 and will be performed at a similar level in FY 1994 and FY 1995.

Based on the workload estimates established in the GAO study, and assuming a consistent level of workload through the succeeding years, we estimate our costs at approximately \$9.6 million for FY 1992, \$10.2 million for FY 1993, and \$10.8 million for FY 1994 and FY 1995.

DIETARY SUPPLEMENTS

Mr. MCDADE. Also, since Dr. Kessler has indicated at our previous subcommittee hearing held on October 18, 1993 on dietary supplements and herbs a strong need for FDA to vigorously regulate and enforce health risks to people from dietary supplements, how does the adverse impacts and risk data compare to FDA approved drugs?

RESPONSE. The drug approval process requires sufficient testing that identifies adverse effects and contraindications. Consumers are provided this information on the label or label inserts. There is currently no systematic evaluation of the safety of products marketed as dietary supplements.

Dietary supplements are considered to be foods, and there is no risk/benefit assessments for foods because there is no known acceptable risk that should be attributed to foods.

Mr. MCDADE. Dr. Kessler, several months ago you testified before the Subcommittee on the dietary supplement issue, which we all know, is of great concern to the American public. Tell us, what progress has the FDA made in resolving the "dietary supplement wars" since you testified before us on October 18?

RESPONSE. The FDA published the final rules on Dietary Supplements on January 4, 1994. In that Federal Register document the FDA clarified the label and labeling requirements for vitamin and mineral supplements and the eligibility requirements of dietary supplements for health claims and other types of claims. In general, the agency required that dietary supplement manufacturers label their products in the same manner as all other foods and that all claims on their products be substantiated as we would expect for other foods.

The regulations did not affect a manufacturer's ability to market a product as long as it is safe. If a manufacturer wishes to market a product with nutrition or health claims, these regulations require that the claim is truthful. Other claims are covered by the general provisions in the FD&C Act which require that the claims be truthful and not misleading. In addition, the Commissioner has advised that FDA will not take regulatory action under the food additive provisions absent a safety or significant consumer deception concern, even though the unapproved food additive charge does not legally require a showing of an actual hazard or deception.

Mr. McDADE. Dr. Kessler, could you please tell the Subcommittee the extent to which FDA resources have been expended on regulatory actions with respect to dietary supplements? This answer should include, but not limited to:

Staff resources necessary to develop the June, 1993 and December, 1993 Federal Register notices on dietary supplements;

Field resources, broken down by FDA office, to enforce the Federal Food, Drug, and Cosmetic Act with respect to Dietary Supplements during 1993 and January through March of 1994; and

Staff resources, including consumer safety officer field time, to develop the report, "Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace," which you presented at a July, 1993 hearing before the House Energy and Commerce Health Subcommittee.

RESPONSE. We estimate that 7.5 FTEs were required to develop the Federal Register notices on dietary supplements. We estimate approximately 0.2 FTE was required to develop the report. Our estimate of field resource utilization for FY 1993 is 79 FTEs, all in the Office of Regulatory Affairs. We estimate a usage of about 79 FTEs for FY 1994.

McDade. It has been reported that during the Wasman hearing, Dr. Kessler, you stated that "for every dietary supplement in the marketplace that may have some value, there are 100 or 1,000 that are worthless." How does this statement square with your agency's earlier comment in its 1993 Section 409 report to Congress that "the vast majority of dietary supplements consumed today do not raise serious health or regulatory concerns."?

RESPONSE. The report "Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace," provided during the hearing, contains the statement "Thousands of unsubstantiated claims are being made about hundreds of dietary supplements." This statement was part of FDA's conclusions about the July 29, 1993 report that was presented to Congress.

The traditional vitamin and mineral products that comprise more than 80 percent of the multibillion dollar dietary supplement market raise no serious concerns as long as they are sold without disease prevention or treatment claims or unauthorized health claims, have potencies that do not raise safety concerns, and are manufactured using appropriate quality control standards.

The economic value of some of these products is questionable but they do not raise serious health or regulatory concerns. However, the conclusions of this report apply to the other approximately 20 percent of the dietary supplements in the marketplace which sometimes do raise concerns about safety or consumer deception. Many of these products have no recognized role in nutrition or health, frequently bear express or implied disease prevention, treatment, or unauthorized health claims, and have been marketed for specific therapeutic or reduction in disease risk purposes.

Mr. McDADE. Do you feel your agency's enforcement activities are adequate, if you believe that only one-tenth, or one-hundredth of all dietary supplements marketed may have some value?

RESPONSE. Regulatory actions are on a case by case basis with the burden of proof resting with the Agency. The Agency does not take regulatory actions against every product. FDA's policy as stated to Congress in the "Enforcement Report" and in my testimony at the July 29, 1993 hearing on dietary supplements before the Subcommittee on Health and the Environment is that it will not bring an action against a dietary supplement unless there is a basis for concern about the safety of the product or significant consumer deception.

The Agency has successfully regulated many of these products as evidenced by the list of enforcement actions taken under the Health Fraud Program that was provided as part of my testimony on July 29, 1993. There are, however, many competing public health priorities facing FDA, and the Agency must divide its scarce resources among all of the important issues that demand our attention.

Mr. McDADE. Dr. Kessler, when you appeared before us, you set out a number of products which you believed presented violations of the Federal law. How many of those products has FDA taken action against, either before our hearing or since?

RESPONSE. The products displayed at the hearing represented examples of the types of products that have unsubstantiated health claims in their labeling and would be typical of those which FDA would attempt to correct. From January through December 1993, 31 warning letters and 3 seizure actions for dietary supplements were recommended.

EVENING PRIMROSE OIL

Mr. McDADE. Is it true that the FDA gave 60 employees awards for their unsuccessful efforts to remove evening primrose oil from the market? Were these cash awards?

Response. The Food and Drug Administration did recognize 60 employees or former employees for their outstanding performance in the Evening Primrose Oil—EPO—litigation in California and Maine.

The process began in New York in 1988, spanned several years and resulted in the District Courts for California in 1989 and Maine 1991 declaring that the EPO seized in these cases was an unsafe food additive and violated 21 U.S.C. 342(a)(2)(c). The U.S. Court of Appeals for the Ninth Circuit rejected the company's appeal and upheld the California court ruling on April 7, 1992. In November 1992, certiorari was denied by the U.S. Supreme Court for the California EPO case. The company chose not to appeal the decision of the District Court in Maine.

The long hours, hard work and exceptional coordination efforts required by all the employees involved in these actions were recognized with a group Commissioner's Special Citation Honor Award, not cash awards.

NEW DRUG APPROVAL ACTIVITY

Mr. McDADE. On page 3 of Dr. David A. Kessler's written statement mention is made about the fact that 370 new drug, generic drug, and biologic product applications were approved in 1993. How many total applications were received by FDA during 1993?

RESPONSE. During 1993, the Agency received a total of 457 drug and biologic applications. The Agency received 86 original NDAs, 332 original ANDASs, and 39 PLAs.

Mr. McDADE. What is the average new drug processing approval time?

RESPONSE. The average or median review time for new drug approvals in 1993 was 24.1 months. The average (median) review time for the major biological products was 23.9 months in 1993. That is the time from receipt to approval.

Mr. McDADE. What is FDA's current backlog time for drug application approvals?

RESPONSE. I assume you mean the drug application overdue backlog. At the end of 1993 there was a NDA backlog, that is applications pending more than 180 days, of 39 NDAs. The NADA backlog was 39 applications. As of March 1, 1994, the Biologics backlog was 3 PLAs.

Mr. McDADE. Of the 370 approvals stated how many were generic? and how many were biologic products?

RESPONSE. Of the 370 approvals in 1993, 249 were generic drug approvals. There were 51 biological product approvals, and 70 new drug approvals, including 25 approvals for new molecular entities drugs distinctly different in structure from those already on the market.

Mr. McDADE. What was the average total cost to reach approval for the 370 products listed for the manufacturers and for FDA as well?

RESPONSE. FDA does not have information on the manufacturers' average total cost per approval was. The Arthur Andersen accounting firm recently completed a study for the Agency that estimated the standard cost for the various type application reviews. I will be happy to provide this information for the record

[The information follows:]

Type application:	Estimated standard cost per application
NDA with clinical data-NME	\$887,000
NDA with clinical data-Non-NME	298,000
PLA	1,078,000

Generic applications were not included in the Arthur Andersen study. We estimate that the average ANDA review costs approximately \$25,000 per application review. The average total FDA cost to reach approval for the 370 products in 1993 was approximately \$262,000 per application.

MEDWATCH PROGRAM

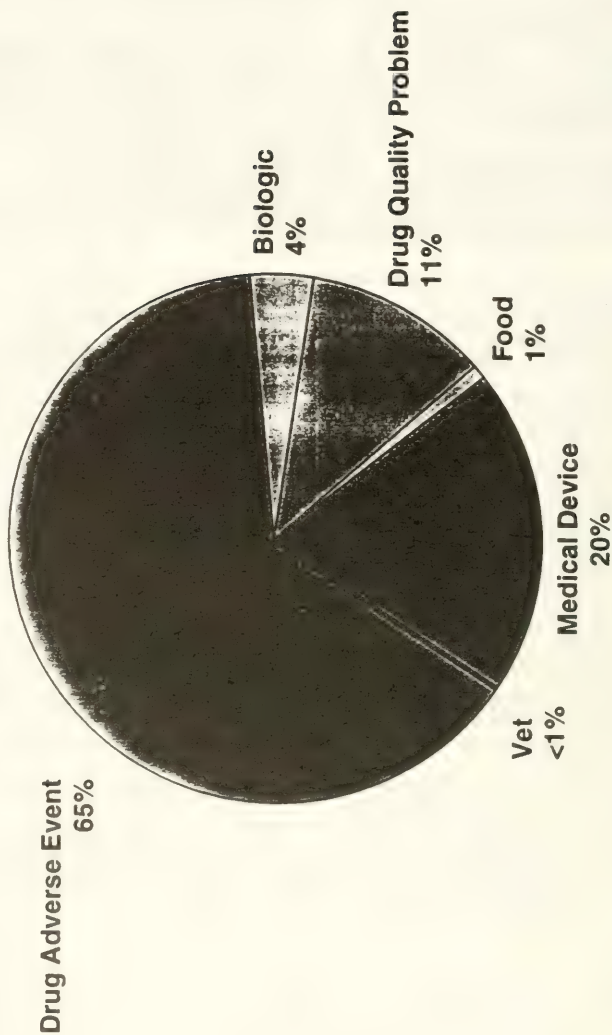
Mr. McDADE. On page five of Dr. Kessler's written statement indicates that he is pleased with the progress and improvement being made on the MEDWatch adverse reporting systems for drugs, biologics, and medical devices. It would be most helpful to receive a report with some degree of specific findings from the most recently completed MEDWatch program report reflecting some of the major adverse impacts including deaths caused by approved drugs, biologics, and medical devices.

RESPONSE. I will be happy to provide this information for the record.

[The information follows:]

Type of Voluntary Report

156

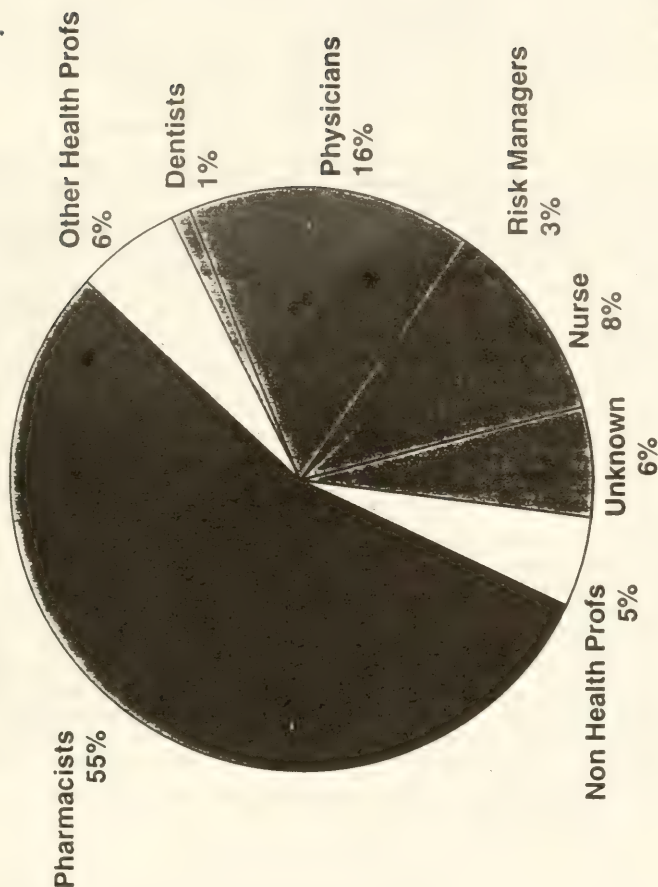


(As of February 28, 1994)

Total = 6755

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Type of Reporter



Total = 6755

(As of February 28, 1994)

MEDWATCH PROGRAM

The MEDWatch program was launched on June 3, 1993. Through February 28, 1994, the program had received 6,755 reports. Of those 65 percent were an adverse drug event (Figure 1). Fifty-five percent of the reports were submitted by pharmacists and 16 percent by physicians (Figure 2).

MEDWatch encourages health professionals to report serious adverse events. Serious is defined as a patient outcome of death a life-threatening condition, hospitalization (either initial or prolonged), disability, congenial anomaly or where medical or surgical intervention is required to prevent permanent impairment or damage. Of adverse event reports for drugs and biologics 69 percent have been serious while 39 percent of medical device reports were serious. This is what would be expected since deaths and serious injuries that occur in a user-facility would be reported to FDA via the mandatory system and wouldn't go through MEDWatch.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

Mr. MCDADE. Dr. Kessler, it is my understanding that your agency is considering consolidating several regional research laboratories into the National Center for Toxicological Research, which is located in Arkansas.

Would you please provide the Committee with any reports prepared by FDA staff regarding the existing and previous performance of the Center so that we can better understand the consequences of the proposed consolidation?

RESPONSE. To clarify what may be a misunderstanding, FDA is not considering consolidating other parts of the Agency into NCTR. There is serious consideration being given to utilizing the space and the buildings already owned by the Department at the NCTR site to locate some parts of FDA's field organizations. Such a move should save millions of dollars now spent to lease and maintain these facilities in urban areas but would also require investment to renovate space at NCTR. No final decision on this possible field consolidation has been made yet.

There are no formal studies conducted by FDA staff regarding the performance of NCTR. The only previous studies of which I am aware were associated with problems of direction the Center encountered in the mid-1970's. Those reviews were associated with the performance of the leadership at that time, not the performance of the Center.

There have been several external reviews of performance. In May 1991, the Advisory Committee on the Food and Drug Administration issued a report in which they evaluated the entire Agency, including NCTR. Following that report, there has been a massive redirection of the work of NCTR to align more completely with the regulatory mission of FDA. We have implemented a process of external reviews of the NCTR programs, tied to relevancy reviews by FDA staff. Since the 1991 report, there have been five finalized reviews, and three now are scheduled for 1994.

The Advisory Committee informally reviewed progress in June 1992, with a report entitled "*One Year Later.*" In that report, the Committee indicated that there had been a positive step to "utilize better the excellent scientific capabilities of the National Center for Toxicological Research." I will be happy to provide copies of these reports to the Committee.

[CLERK'S NOTE: Reports have been provided to the Committee but have not been included here because of their volume.]

CELLULAR TELEPHONES

Mr. MCDADE. Could you please tell the Subcommittee how many cellular telephones the FDA owns and/or rents?

RESPONSE. The Agency has purchased 326 cellular telephones and does not lease any cellular telephones.

Mr. MCDADE. What is the annual cost of purchase and rental of these instruments and cost of air time?

RESPONSE. The average cost for cellular telephones is \$300 each and they have been purchased over several fiscal years for a total capital investment of \$97,800.

The average monthly service cost per cellular telephone is \$17 for an annual cost of \$66,504.

The average annual airtime cost per cellular telephone is \$680 for a total annual cost of \$221,680.

Mr. MCDADE. Has the FDA issued any formal guidance to employees about when these phones should be used and when they should not? For example, have you issued formal rules to employees that they are not allowed to make personal calls, either local or long-distance, on government cellular phones?

RESPONSE. The Agency has issued Staff Manual Guide, FDA 2760.5 STANDARDS FOR CELLULAR TELEPHONES which prescribes the policy and procedures governing the acquisition and utilization of cellular telephones. A section of User Responsibility states that "All calls placed on cellular telephones must be certified monthly as official business and necessary to the interest of the Government." I will provide for the record, a copy of the standards.

[The information follows:]

**STAFF MANUAL GUIDE
FOOD AND DRUG ADMINISTRATION****GUIDE****FDA 2760.5****OFFICE OF INFORMATION RESOURCES MANAGEMENT****STANDARDS FOR CELLULAR TELEPHONES**

1. Purpose
2. Policy
3. Responsibilities
4. Procedures

1. **PURPOSE.** This guide prescribes the policy and procedures governing the utilization and acquisition of cellular telephone services and facilities.
2. **POLICY.** It is the policy of the Food and Drug Administration (FDA) to provide cellular telecommunications services and facilities for Agency activities at the minimum total cost to the Government, consistent with requirements for capacity, efficiency of operation, reliability of services, security, and program objectives.

Cellular telephone equipment and service for Agency activities will be provided at the least cost to the Government, consistent with requirements for efficiency of operation, reliability of service, and security.

3. **RESPONSIBILITIES.** The Office of Information Resources Management, Office of Management, has the overall responsibility for the management and coordination of telecommunications management, including:
 - a. Development and implementation of an ADP and telecommunications plan and budget.
 - b. Development of standards to assist in linking data and systems across Center and program lines.
 - c. Design, acquisition, management, and evaluation of all Agency telecommunications systems.
 - d. Review and approval of all Agency Procurement Requests, contract proposals, Interagency Agreements, and requisitions involving telecommunications and automated systems.
 - e. Consultation and technical assistance in the selection and use of telecommunications equipment and services.
4. **PROCEDURES.**
 - a. **Criteria for Providing Cellular Telephones in Private Automobiles.**
 1. Cellular telephones in privately owned vehicles (POVs) will be provided to Agency personnel for official Government business.

Requests for cellular telephones to be installed in POVs must be approved by the Associate Commissioner for Management (HFA-1).

2. Requests for cellular telephones installed in POVs in field offices must be approved by the District Director, the Associate Commissioner for Regulatory Affairs (HFC-1), and the Associate Commissioner for Management (HFA-1).
3. Only one cellular telephone per car will be provided unless special needs are justified and approved through the Associate Commissioner for Management.

b. Criteria for Providing Portable Cellular Telephones.

1. Portable cellular telephones will be provided to Agency personnel for official Government business, including undercover/surveillance activities, raids, vehicular travel, investigations, and natural disasters, etc. Requests for portable cellular telephones must be approved by Centers Executive Officers, and by Division of Information Management, Telecommunications Management Branch (HFA-57). Executive Officers shall base their approval of cellular telephones on official job related responsibilities.
2. Portable, state-of-the-art, cellular telephones will be provided at the least expense to the Government consistent with requirements for efficiency of operation, reliability of service, and security.

c. Requests.

1. Requests for cellular telephones shall include the following information:

Cellular Telephones in POVs

- a. Agency activity and name of user.
- b. Office telephone number, contact, and room number.
- c. Make, model, and year of automobile.
- d. Location of antenna (trunk or window mount).

Portable Telephones

- a. Agency activity and user, i.e., compliance, investigations, District Director, etc.
- b. Address, contact, and telephone number.
- c. Quantity of telephone(s).
- d. Type of telephone(s) - (hand-held, transportable, and cellular fax units), and wattage (i.e., 0.6 or 3.0).

2. Requests should be forwarded to the Center IRM Director for review and to the Executive Officer for approval.

d. User Responsibility.

1. Long distance calls must be placed over the FTS2000 network. Instructions on how to program cellular telephones to access the FTS2000 network can be obtained from the Telecommunications Management Branch (HFA-57). The cost for long distance calls placed over non-FTS2000 networks will be the responsibility of the Center/Office.
2. All calls placed on the cellular telephones must be certified monthly as official business and necessary in the interest of the Government. The Government will be reimbursed by check or money order payable to the Food and Drug Administration, for the cost of calls that are not official business. The records for all calls and the certification for all calls must be retained for two years.
3. The monthly cellular usage charges for portable and car telephones will be billed to the requesting Headquarters/Field/Center/Office.
4. Purchase of cellular telephones will be the responsibility of the requesting office in Headquarters and the Field.
5. Reimbursement to the Agency for the purchase price of a lost cellular telephone through negligence will be the responsibility of the authorize user.
6. Personnel separating from the Agency who have car telephones and/or portable telephones will return them to their designated IRM Officer before departure. Car telephones will be de-installed before departure or within a week after separation. Arrangements with the local cellular vendor for de-installation should be scheduled one to two weeks before separation date.

e. Reimbursement for Official Use of Privately-Owned Cellular Telephones.

1. Effective July 1, 1993, no reimbursement will be made for calls made with privately-owned cellular telephones.
2. Prior to July 1, 1993, reimbursement requests for calls made on privately-owned cellular telephones must be approved by the Executive Officer and the Center Director or Associate Commissioner.

Mr. MCDADE. Are efforts made to collect from employees any amounts they may owe for personal use of these phones?

RESPONSE. The Standards provide that the Government will be reimbursed by check or money order payable to the Food and Drug Administration for the cost of calls that are not official business.

Mr. MCDADE. How much do you collect annually from personnel for their personal use of phones?

RESPONSE. The Agency was reimbursed approximately \$3,000 in FY93 for unofficial cellular telephone usage.

Mr. MCDADE. Where are those funds deposited?

Dr. KESSLER. These funds are deposited in a Miscellaneous Obligating Document—MOD—in the Office of Financial Management.

USER FEES

Mr. MCDADE. The Administration's proposed FDA appropriation language reads, in pertinent part:

. . . and in addition, \$252,000,000 to be credited to this appropriation, from fees established and collected to cover the costs of regulation of products under the jurisdiction of the Food and Drug Administration, to remain available until expended.

In addition, fees pursuant to section 736 of the Federal Food, Drug, and Cosmetic Act may be credited to this appropriation and remain available until expended in accordance with section 736(g) of such Act; . . . Provided further, that fees derived from applications received during fiscal year 1995 shall be subject to the fiscal year 1995 limitation.

The fiscal year limitation referred to is \$75,000,000. Even if the full \$75 million were to be raised under this authority, that leaves \$177 million to be raised under the general user fee statute, 31 U.S.C. 3302(b), all such collections must be deposited in the general fund of the Treasury, and would not be available for agency use. Is the quoted appropriations language intended to override this requirement? And, if so, is it not legislation on a general appropriations bill, and therefore subject to a point of order under House Rule XXI-2(b)?

RESPONSE. The \$252 million you reference in your question does not include the funds for the prescription drug user fees. The prescription drug user fees, which we estimate to be about \$79 million in 1995, are in addition to the \$252 million you reference.

The \$252 million referred to has two components—\$24 million proposed to be collected under new legislative authority that would allow the funds to be collected and used to fund enhancements in our medical device evaluation activities, and \$228 million in new user fees to maintain current FDA activities.

We are still developing a plan for raising the \$228 million. There are many complex issues associated with collecting substantial new user fees. We are looking at possible candidates for such fees. We are looking at virtually all FDA activities except those covered by specific current or proposed user fee authority. Activities left include food and animal drug activities of the agency, activities at the National Center for Toxicological Research, generic and over the counter drug programs, blood banks, most of our import and domestic inspection activities, and our enforcement and compliance activities.

You are correct that, absent specific statutory authority, any collections made under the general user fee authority of 31 U. S. C. 9701 would have to be deposited in the miscellaneous receipts of the treasury rather than kept by the agency for its expenses. That is why the proposed appropriation language states that the \$252 million from new fees the agency would impose should be credited to FDA's appropriation and remain available until expended.

IRRADIATED CHINESE FRESH GARLIC

Mr. FAZIO. Three California fresh garlic producers have submitted two well-documented letters to the FDA (dated Feb. 16 and March 15, 1994, and addressed to Dr. Fred R. Shank, director of the FDA's Center for Food Safety and Applied Nutrition) concerning the importation of large amounts of irradiated fresh garlic from the People's Republic of China. Is the witness aware of these letters?

RESPONSE. Yes, FDA is aware of these letters on irradiated garlic.

Mr. FAZIO. The California producers have presented much factual information in support of their claim that:

Chinese garlic is being irradiated in China to prevent it from spoiling through "sprouting" once it is shipped to the United States.

The Chinese product is being entered into the U.S. Commerce without the markings required by law and FDA regulations that will alert consumers to the fact that the garlic has been irradiated.

Importers and other handlers of imported Chinese garlic are intentionally not labeling this imported product as having been irradiated to avoid discouraging potential customers who typically would not buy fresh garlic that has been irradiated.

One out of every three pounds of fresh garlic consumed in the United States in 1993 was imported from China. The California producers fear that the consuming public's confidence in all fresh garlic producers will be hurt once they realize that a large amount of the fresh garlic available to them in grocery stores, etc., has been irradiated without notice to the public.

Does the FDA have any information that would refute these claims?

RESPONSE. The factual information supplied by the attorney for the garlic producers consists of the following: a list of garlic importers and exporters; two letters from Congressman Don Edwards to the Ambassador from China requesting information on garlic from China and whether it is irradiated and a response from the Chinese ambassador stating that Chinese exported garlic is not irradiated; memoranda—two of which were titled Declarations—from three individuals reporting on conversations with unnamed individuals who stated that some Chinese garlic was irradiated and stating that samples of garlic showed a discolored sprout bud; a declaration that a garlic producer who visited irradiation facilities in China and discussed irradiation of garlic with employees at the facilities; a letter—with the source and recipient deleted—offering to sell someone garlic that has been x-rayed. The letter also states that the garlic does not bear any trace of chemicals used to inhibit sprouting but does not state how this determination was made.

The attorney claims that the imported garlic has been irradiated and is not properly labeled. FDA has no information at this time that would prove whether the garlic has been irradiated and can neither support nor refute the claims made by the attorney.

Mr. FAZIO. The California producers' March 15 letter reports a telephone conversation the producers' international trade attorney had with the product policy division director in the FDA's Office of Pre-Market Approval on March 2 concerning the producers' Feb. 16 letter. According to that report, this FDA official, Dr. George Pauli, told the producers' attorney:

The information conveyed in the Feb. 16 letter was enough to create a mere suspicion that Chinese garlic was being imported and distributed into U.S. commerce without meeting the FDA's regulations concerning irradiated produce;

This information, however, was not proof of improper conduct, and without such proof provided by citizens, the FDA could and would do nothing about Chinese imports.

The FDA has not developed any method by which it could determine whether a food product—and fresh garlic in particular—had been subject to radiation, and that the FDA was aware of no such procedure having been developed by the private sector.

The FDA is unable to enforce U.S. law or its own regulations on the irradiation of food products, generally, and fresh garlic in particular.

The FDA had last been asked to enforce its irradiation regulations against an imported food product (fresh shrimp) more than five years ago, but the FDA was unable to do so because of its inability to prove that the imports in question had indeed been irradiated.

Has the FDA concluded that it cannot enforce its regulations pertaining to fresh food irradiation?

RESPONSE. FDA has not reached that conclusion. FDA enforces its regulations in a variety of ways, primarily by inspection. FDA also supports research to develop methodology that could be used to determine whether a food has been irradiated. It recognizes, however, that the effects of irradiation on food are very small and of a type that is not necessarily unique to irradiation. That, in fact, is a major reason why FDA concluded that the process is safe.

We believe that it is important to point out, however, that Dr. George Pauli did not tell the producer's international trade attorney that "without such proof provided by citizens, the FDA could and would do nothing about the Chinese imports". FDA enforcement actions generally do not result from proof provided by citizens. He did tell the attorney, however, that FDA could not impose a regulatory sanction without proof that the law has been violated and that his submission did not provide evidence that irradiated garlic is being imported without proper labeling.

Mr. FAZIO. According to the California garlic producers' letters, the only way to prevent fresh garlic from sprouting is to either fumigate it, which leaves a easily detectable residue, or irradiate it, which leaves no trace other than the dead sprout

in the garlic cloves. It thus appears that it would be relatively easy for the FDA to determine whether fresh garlic had been subject to irradiation: if a garlic clove on inspection revealed a dead internal germ sprout and no chemical residue, the sprout would have been killed by irradiation. According to the March 16 letter, the FDA official stated that there were dozens of ways the germ sprout in fresh garlic could be killed besides the two identified by the California producers, and this was the reason the FDA could not enforce its irradiation regulations with respect to fresh garlic.

Could the witness verify that official's claims, and report back to the committee regarding the questions raised by the California garlic producers' letters?

RESPONSE. We know of no basis for the claim that if certain chemical residues have not been found, then a chemical fumigant could not have been used. Nor can we be certain that no physical process other than irradiation can inhibit sprouting.

Generally, whether residues can be detected will depend on the particular chemical, treatment levels, the time since treatment, conditions of storage, the analytical methodology used, and the particular food treated. The submissions FDA received do not state the basis for the producers' conclusions. In general, we cannot conclude that a food has been treated by a particular process, such as irradiation, simply because there is no proof of what caused the effect.

In sum, we have recently received two letters alleging that certain improperly labeled foods are being imported. We are considering these allegations to determine what action would be appropriate.

Ms. ROUKEMA. Dr. Kessler, should the Congress authorize user fees for improving the responsiveness of the product review and approval process, what assurance can you provide that the process will be improved? Please be specific in the ways in which your agency will be accountable to the industry who are paying to facilitate the review process. Also, who are the beneficiaries of an improved review and approval process?

RESPONSE. The best answer I can give is the experience we have had with the Prescription Drug User Fee Act. In the process of developing that legislation, substantial new goals were negotiated between FDA, industry representatives, and the Congress. Those goals were memorialized in two letters that I sent to Members of Congress, and which were incorporated into the congressional report on that legislation. I believe we have done a good job of conscientiously striving to meet those goals.

The implementation of this new statute has been a very demanding undertaking. It defined many old processes in new ways, and demanded that we make substantial adjustments in how the agency does business in order to accommodate the requirements of this Act.

Regarding the recruiting goal set out in the letters, we are on target. We have about 180 more FTEs on board now dedicated to the process for the review of human drugs than we had in 1992, before the passage of the Act. We are continuing to recruit aggressively, and incremental our on-board staff dedicated to this process should exceed 350 by the end of this fiscal year.

Backlogs of overdue original new drug applications were reduced from 35 to 6 in our Center for Drug Evaluation and Research, and from 9 to 3 in our Center for Biologics Evaluation and Research, as of January 31, 1994.

The real impact of increased review staff on review times will take a while to show, as it cannot be measured until applications submitted each year have been acted upon. It also takes time to train new staff before they are fully productive in their work.

We do have every reason, however, to expect continued improvement consistent with the Prescription Drug User Fee Act goals. The ultimate beneficiaries of this improved review process are the American people, in that they will have quicker access to promising therapies.

More details on our implementation efforts are contained in two reports to Congress required by the Prescription Drug User Fee Act. I hope they will be issued in the near future.

MEDICAL DEVICE INNOVATION

Ms. ROUKEMA. Dr. Kessler, there is substantial evidence that the FDA regulatory process is having at least two negative effects:

The process is causing the medical devices industry to lose its competitive edge relative to the EC and Japan.

The process is causing domestic firms to shut down operations and move to overseas locations.

What steps are you taking to strike a better balance between ensuring American consumers with medical devices that are "safe and effective" and maintaining and improving the current and historical U.S. dominance of medical device innovation, development, and commercialization?

RESPONSE. I will be happy to provide this information for the record.

[The information follows:]

COMPETITIVENESS IN THE MEDICAL DEVICE INDUSTRY

FDA is concerned about U.S. competitiveness as well as the assurance of safe and effective medical devices. We are working with the Department of Commerce to help the U.S. industry compete globally by harmonizing U.S. and foreign regulatory requirements which will "level the playing field," in countries such as Japan, Canada, and Australia. We are changing our Good Manufacturing Practices regulations to be compatible with the comparable European requirements. We are working with Europe and other regions on mutual recognition agreements to help U.S. industry avoid the necessity of meeting differing regulatory requirements.

The U.S. medical device industry remains competitive as is evidenced by a new industry report.¹ According to the report:

The U.S. is the world's largest net exporter of medical devices, with a \$4.7 billion trade surplus in 1993, an increase of 15 percent over the 1992 surplus. The U.S. medical device trade surplus with the EC grew to \$1.7 billion in 1993, while the U.S. trade surplus with Japan grew to \$274 million;

In 1993, employment in the U.S. medical technology industry grew by approximately 3 percent, while the comparable growth in Europe and Japan was only 1 percent.

The U.S. Department of Commerce projects U.S. medical device industry growth at a rate of 8 percent over the course of 1993, or nearly three times faster than the growth expected for U.S. industry overall;

In 1993, U.S. owned companies accounted for the lion's share of the global market for medical technology with a 52 percent share of the global market; and

The U.S. medical technology industry has been a significant contributor to U.S. economic growth in recent years, in terms of U.S. production growth, job growth and export growth. Export growth accounts for a robust 32 percent of production growth during the period 1989-1993.

These data reflect a strongly competitive domestic medical device industry.

PUBLIC/PRIVATE SECTOR RELATIONS

Ms. ROUKEMA. Dr. Kessler, President Clinton has made it clear that part of his domestic economic agenda involves a closer working relation between the public and private sectors. Even so, your agency has the reputation of being the federal agency with the highest barriers to public sector, private sector relations. This was clearly an area identified by Chairman Dingell's committee in his report "Less than the Sum of Its Parts." What steps are you taking to capture the synergy that can materialize if your agency and the industry you are charged with regulating were to work in a collaborative versus adversarial ways?

RESPONSE. FDA has taken a number of steps over the past year that I am convinced will reduce the "barriers" you refer to. I view these steps as falling into three categories: first, spending our product review resources more wisely; second, giving the medical device industry a clearer set of rules by which to market their products; and third, placing greater emphasis on what I refer to as "customer service" in our communications with industry executives. Let me highlight the progress we've made in each area.

As the job of our Center for Devices and Radiological Health has gotten bigger, we have come to realize that to sustain productivity and better manage our resources, we must work smarter. One example is a "refuse-to-accept" policy put in place last summer by the Center, under which poor quality premarket submissions are rejected. The result is agency resources are not squandered; they are applied only to those submissions complete enough to warrant the expenditure of review resources.

Another new policy calls for accelerated scientific review of innovative and clinically important devices to enable them to reach the marketplace faster. And finally, the Center has redistributed its in-house scientific resources to help reduce application backlogs and processing times. Let me give some results.

¹ The Global Medical Device Market Update, Health and Industry Manufacturers Association (Jan. 1994).

For the first six months in calendar year 1993, the number of premarket notification applications, or 510(k)s, coming into the device center exceeded the number going out. For the period July-December, we saw the numbers turn around: 2,971 in and 3,122 out. And this trend continues. This January, incoming applications numbered 426; 554 were processed. And in February, 497 were received with 699 acted on. Last December, the number of applications awaiting review beyond 90 days was 1,978; by February, that number dropped to 1,468.

We've also put considerable effort into elucidating the requirements device manufacturers must meet in order to market their products. One of the key criticisms in Chairman Dingell's report centered on the poor quality of clinical data in premarketing applications. To remedy this, we have held a national workshop and a nationwide teleconference and spelled out how to properly design and conduct clinical studies and to collect, analyze and present the data yielded by human research. In addition, FDA has issued guidances that give manufacturers the marketing requirements for a number of specific device types.

We plan soon to consult with the industry on an agency developed process for determining if new applications are needed when changes are made to already-marketed devices, an issue that for some time has caused concern and confusion. In addition, to make manufacturers aware of our streamlined export certification procedures, we mass mailed an information letter to the industry.

In keeping with the goal of more open communications, the Center has established a "hard copy" and electronic docket from which anyone in the industry can access policy and regulatory documents and information about FDA operations. Complementing this system is another known as "Flash FAX" from which device firms can request information on virtually every aspect of FDA's medical device program and have that information faxed to them instantaneously. In addition, the Center's small business assistance organization operates a system that enables manufacturers to obtain the status of their applications in the review queue.

Taken together, these steps represent a concerted effort to de-mystify and bring greater clarity to FDA's regulatory processes for medical devices. Early signs point to positive results. We remain optimistic that as these and other new policies take root, our relationships with industry will continue to improve.

CONTRACTING FOR PRODUCT REVIEW

Ms. ROUKEMA. Dr. Kessler, with President Clinton's promise to reduce the size of the Federal Government by 252,000 jobs, why hasn't your agency been more aggressive in contracting out for product review services rather than building in-house capacity to conduct product reviews? What are the advantages to contracting for such services? What are the disadvantages? Should you be mandated to contract for review services, how would you structure such a system?

RESPONSE. In fact, FDA has been fairly aggressive in contracting out those things that it can, where contracting is more cost efficient for the Federal Government, and where the functions to be contracted are non-controversial. As a regulatory agency, however, many of our functions, including product evaluation, are considered inherently government work. We will continue to look at opportunities as they present themselves.

First let me mention briefly contracts in non-controversial areas, and then turn to product review. In non-controversial areas, FDA has awarded contracts that, over time, have replaced a number of Federal employees. At the National Center for Toxicological Research in Arkansas, where our major work is research, over half of the work force is employed by contractors who work in government facilities—about 300 contract employees compared to about 250 Federal employees. Similarly, in recent years most of our document rooms in various FDA components have been converted to contract operations. We have been vigilant to make such conversions wherever they make sense for the taxpayer.

FDA contracts with States for regulatory services, including food safety inspections, animal feed safety, and radiological product testing. We also plan significant State participation in the required inspections of mammography facilities as the Agency implements the Mammography Quality Standards Act.

The area of product review, which you ask about directly, however, has been subject to some controversy. In an initiative of the previous Administration, FDA began a very small pilot program to test the possibility of contracting some of our more routine new drug application reviews. There was a great deal of concern about this in the Agency as well as externally. The pilot is ongoing and is being monitored carefully.

Subsequent to the initiation of that pilot project, however, the Prescription Drug User Fee legislation was enacted. The House Report on that Act makes it clear that

it was the intent of the drafters that user fee revenue not be used to pay for contracts for drug review. That report, House Report 102-895, states that user fees may not be used to pay for "contracts or organizations or individuals outside the FDA to engage in the process for the review of human drug applications. Such contracts may not be funded through money raised under HR 5952." In our current budget environment, where all additional funds available for the drug review process come from user fees authorized under the Prescription Drug User Fee Act, we are not in a position to fund such contracts.

In terms of the advantages or disadvantages of contracting out for reviews, I really think we need more time with the small pilot contract we have under way before drawing any conclusions or speculating about the best way to structure contract reviews.

DEVICE APPROVAL TIMES

Ms. ROUKEMA. Dr. Kessler, this Committee is aware of many instances where a domestic medical devices company had developed a new product and have received approval to manufacture and sell this product in the EC within a two-year period. Approval to manufacture and sell this same product in the U.S. takes 4-years! How do you explain this time discrepancy? What steps are you taking to correct this gross imbalance?

RESPONSE. It must first be noted that the EC is just beginning to implement a pan-European device approval process. Up until now, most approvals were on a country by country basis where the level of regulation varies greatly from essentially no government oversight to systems with many elements similar to the FDA.

It is impossible to address different approval times without specifics about the device, the manufacturer, and the other country involved. Clearly, marketing approval in a country with virtually no requirements to demonstrate safety and effectiveness will be faster than in the U.S. where the medical device laws require FDA to assure safety and effectiveness before marketing.

MEDICAL DEVICE BACKLOG

Ms. ROUKEMA. Dr. Kessler, how does backlog of medical device submissions compare between 1992 and 1993?

RESPONSE. At the end of FY 93, the backlog of 510(k)s—applications that FDA has had under review for over 90 days—stood at 1,894. The backlog was 331 at the end of FY 92. For PMAs, the backlog at the end of FY 93—applications that FDA had under review for over 180 days—was 45. The comparable number for the FY 92 backlog was 36 PMAs. The backlog of PMA Supplements—also measured as the number of applications that have been under FDA review for over 180 days—grew from 97 at the end of FY 92 to 174 at the end of FY 93. There is no appreciable backlog of IDE or IDE Supplements, as virtually all of them are reviewed within the 30-day statutory time frame.

Ms. ROUKEMA. What is your agency doing to reduce and ultimately eliminate this backlog?

RESPONSE. FDA is taking steps on three major fronts to deal with this backlog situation. First, it has instituted several management initiatives that will use review resources more efficiently. These initiatives include triaging of 510(k) applications, so the "easier-to-review" applications are handled by consumer safety officers or technicians; piloting the use of a streamlined delegation of sign-off authority in one review division; implementing a "refuse to accept" policy for grossly deficient applications; and a greater reliance on adherence to voluntary standards/guidelines for certain types of devices.

The second approach has been to add resources to the device review program. One aspect was to temporarily reassign FTEs and expertise from other parts of CDRH to review 510(k) applications, the other was to quickly hire, and put to work, the additional FTEs that were given to FDA in FY 94 for the medical device premarket review program. Since the beginning of FY 94, almost 100 employees have been hired by CDRH. While all of these new hires are not yet fully productive, the rate of growth in backlog has leveled off, and backlogs have actually declined for 510(k)s in the first four months of FY 94.

The third area is the development of a user fee proposal that would raise \$24 million to fund the hiring of additional staff to apply to the premarket review program. Over the last six months, FDA has met with industry representatives to develop a proposal that provides the resources that FDA needs, assures industry that FDA will meet specific performance goals within two years, and has a fee structure that does not adversely affect the smaller members of the industry. Currently, Congress is drafting proposed legislation which could make these fees a reality before the end

of this fiscal year. Explicit in the user fee agreement is the elimination of all backlogs within two years of the initiation of the fees.

MEDICAL DEVICE PRIORITIES

Ms. ROUKEMA. Dr. Kessler, it is generally understood that your agency places a higher priority on completing reviews of fundamentally new medical device submissions as opposed to those that are minor modifications of previously approved and marketed devices. Is this an explicit policy of the FDA? If it is, what impact does this policy have on the economic viability of those medical device firms seeking approval of devices that they have historically marketed but have had to make modifications for various reasons such as unavailability of the raw materials used to make the device?

RESPONSE. FDA's Office of Device Evaluation does have an expedited review policy in place for medical devices that offer evidence of a potential for clinically meaningful increased benefit compared to existing alternatives or when the new medical device promises to provide a revolutionary advance over currently available alternative modalities.

To date, there have been about 13 devices identified for expedited review under this policy. All of the identified devices are or were subject to the requirements of the premarket approval program. Devices that are modification of existing devices are usually subject to review under the less stringent premarket notification program. To date, no devices undergoing review under the premarket notification program have been identified for expedited review.

Under the premarket notification program, CDRH receives about 6,500–7,000 marketing submissions annually. The number of expedited reviews is less than 1 percent of the total number of marketing submissions received per year and should not have any significant economic impact on the medical device industry.

MEDICAL DEVICE INNOVATION

Ms. ROUKEMA. Dr. Kessler, the intent the Safe Medical Devices Act of 1990 was to protect the public's health while not impeding innovation. Have FDA's enforcement activities realized this intent? What guidance is your agency providing or planning to provide industry as a means of setting standards so as not to stifle innovation and protect public health?

RESPONSE. FDA enforcement activities have not unduly impeded innovation. I again reference the Health and Industry Manufacturers Report, "The Global Medical Device Market Update" published in January, which points out that the U.S. medical device industry's investment in R&D of 6.7 percent was nearly double the R&D investment of overall U.S. industry in 1992. Furthermore, on a global basis, the U.S. medical industry spends more on R&D—absolutely and as a percent of sales—than its global competitors.

FDA has avoided imposing inflexible mandatory standards on the industry. Only one mandatory standard has been proposed under the medical device legislation. Rather than develop government standards, FDA has worked with voluntary standards development organizations, both domestically and internationally. We work with 394 standards projects, of which 94 are international. We also work with the European standards bodies to help assure that the standards the EC will depend on will be compatible with U.S. practice.

Our written policy on voluntary standards emphasizes the importance of integrating into our regulatory programs the voluntary standards we help to develop.

By relying on voluntary standards we avoid the rigidity and compliance costs associated with government standards. Reliance on voluntary standards is less likely to stifle innovation because such standards are usually developed with active industry and user involvement.

GLOBAL COMPETITIVENESS

Ms. ROUKEMA. Dr. Kessler, American industry in general and the medical devices industry in particular has had to deal with the regulatory requirements of the European Community in order to maintain global competitiveness. What is your agency doing to ensure that you are not adding inefficiency and burden to the existing system and working collaboratively with foreign regulatory agencies to develop a mutually acceptable and beneficial system?

RESPONSE. FDA has already formally proposed changing its medical device GMPs to be harmonized with the quality systems standards to be used by the European Community. Furthermore, we participate in the Global Harmonization Task Force which is working to make the requirements of the U.S., the EC, Japan, and others as similar as possible. Initially, the goals are harmonization of quality system stand-

ards and mutual recognition of inspections. However, mutual recognition of marketing approval for medical devices is a real long term goal. As mentioned before, we are very active in the development of voluntary international standards which often are adopted as regulatory requirements in many countries.

We are in direct contact with regulatory authorities in other countries through a unit established specifically for that purpose under the Safe Medical Devices Act of 1990. This group shares regulatory information with foreign counter parts and works on mutual recognition agreements with foreign governments.

INTERNAL COMMUNICATION IN CENTER FOR DEVICES

Ms. ROUKEMA. Dr. Kessler, what steps is your agency taking to improve internal communication and working relationships between your various offices, i.e., Office of Device Evaluation, Office of Compliance and Surveillance, Office of Science, and Technology?

RESPONSE. The offices within the Center for Devices communicate regularly and have established good working relationships through recurrent interactions. Internal communication is encouraged by senior management and the office directors work together to achieve the Center's program goals. Many interactive meetings are planned among Offices to share information or resolve issues. A weekly Senior Staff meeting is held to discuss program initiatives. Center management scheduled a Senior Staff Go-Away in fall 1993 to discuss the Center's direction and goals for the future, as well as to inspire team building. Recently, Senior Staff reviewed the FY 94 program objectives at a series of three meetings. The staff also makes use of electronic bulletin boards to both notify other Offices of meetings and to stay current on Center events.

In FY 93, FDA established a new Office of Surveillance and Biometrics within the Center for Devices, which combined surveillance and clinical evaluation activities from the Office of Compliance and Surveillance with statistical, epidemiological, and postmarket studies functions from the Office of Science and Technology. The former OCS is now the Office of Compliance, which was reorganized along product lines similar to the structure of the Office of Device Evaluation.

The new OSB instituted Safety Conferences which are open forums for Center staff to meet together on a regular basis to discuss emerging problems, current issues, and perceived safety and efficacy concerns that may be either device-specific or cross-cutting. The goals of the Safety Conferences include enhancement of communications among Center Offices through the exchange of information, integration of post-market surveillance with pre-market data, and identification of emerging device-related problems.

Information shared and discussed at the Safety Conferences can include existing and emerging product approvals, scientific and technical research, database analyses, and compliance issues. Topic selection is open to all staff and every interested and/or knowledgeable person is encouraged to attend.

STATEMENT

BY

DAVID A. KESSLER, M.D.

COMMISSIONER OF

FOOD AND DRUGS

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT,

FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

COMMITTEE ON APPROPRIATIONS

U.S. HOUSE OF REPRESENTATIVES - MARCH 16, 1994

Mr. Chairman, Members of the Committee, it is a pleasure to appear before you again as we present the 1995 Food and Drug Administration budget proposal. Let me introduce my colleagues accompanying me today....

First, let me assure you, our 1995 budget request is lean. Not only are we continuing to take steps to perform our ongoing responsibilities more effectively and efficiently, but we are undertaking important new initiatives aimed at advancing this nation's public health.

Today, I want to highlight some of our activities over the last year, and look ahead to our plans for 1994 and our 1995 budget request.

1993 may be remembered by some as the year of the false reports of syringes in Pepsi cans. That, and other unfortunate episodes put our new Office of Criminal Investigations to the test and we believe it passed with flying colors. The Agency's vigilance and ability to respond swiftly and surely to the kind of unexpected emergencies that pose a threat to the health of Americans remains strong. Whether it be crises contrived by man, or disasters conjured by Mother Nature -- such as the Midwestern floods or the California earthquakes -- FDA must be ready to gather the essential information and deliver the appropriate response. We saw that over the last year.

Some of FDA's activities which, while perhaps less dramatic, are certainly no less important to improving the nation's public health. Let me mention examples from each of our areas of jurisdiction.

I'm pleased to report that we took some important steps with regard to the safety of our food supply. Recently, we announced a new system of preventive controls for seafood called HACCP. This represents a fundamental shift in our approach to food safety. We moved from a system that relied on sporadic inspections and sampling aimed at identifying problems after they occurred to a system that puts in place controls designed to prevent problems from occurring in the first place. Microbiological contamination of food is the most serious food safety problem in this country today and our food safety initiative will improve our ability to address it. This is part of the Administration's commitment to food safety reforms, and we look forward to participating in continued efforts in this area.

In the medical device area, we have made major strides in improving the quality, efficiency and timeliness of device reviews. We are working with industry sponsors earlier to ensure that the data submitted with applications meet our requirements, and we are keeping industry better informed

about the status of their applications. We also believe we have stopped the growth of the backlog of 510(k) applications.

At the same time that we have been improving our traditional device review process, the Center for Devices and Radiological Health (CDRH) has also assumed major new responsibilities. In 1993 we issued interim final rules -- which became final last month -- implementing the Mammography Standards Quality Act. We are committed to assuring women if they need a mammogram there is a system to ensure that the procedure will be performed by well-trained, competent professionals, using quality equipment. We are committed to tackling the serious problem of breast cancer in this country -- American women deserve no less.

The last year has also seen tremendous activity in drugs and biologics. The agency approved 370 new drug, generic drug and biological product applications in 1993. Nine of these drugs were designated as orphans. Important new drug approvals included: Felbamate, the first new epilepsy drug in more than 10 years; and Flumadine, to treat the most serious form of flu.

Two of the 1993 drug approvals were for AIDS-related conditions: Neutrexin for treating moderate to severe pneumocystic carinii a potentially fatal opportunistic

infection, and Gamimune-N for decreasing the frequency of bacterial infections in children with HIV. Additionally, a National Task Force on AIDS Drug Development has been established to remove obstacles and expedite the search for new therapies for AIDS.

On the biologic side, significant approvals include Pulmozyme to treat lung problems in cystic fibrosis patients; and Betaseron for decreasing flare-ups in patients with a relapsing-remitting form of multiple sclerosis.

Both the Center for Biologics and Drugs have been actively recruiting new medical and scientific reviewers as the next step in the Prescription Drug User Fee Act enacted just over a year ago. Although specific performance targets for product review time do not take effect until this year, we're well on track to meet the interim goal set out in the user fee program of eliminating the backlog of applications.

Blood Safety remains a high priority for the Agency. We are closely monitoring compliance with the consent decree we signed with the American Red Cross last year. We have issued new guidelines on various aspects of blood banking and you can expect continued vigilance and close scrutiny of the industry on FDA's part.

Immunization coverage of American children is also high on FDA's list of priorities. We are working with our sister agencies to increase immunization of our children. We are dedicated to reviewing new product license applications for vaccines as quickly as possible so that safe and effective vaccines are available.

As with medical devices, both the Center for Biologics and the Center for Drugs are also undertaking a number of important new initiatives. In 1993, FDA announced it would review the regulation of human tissue used in transplants. This followed investigations indicating that existing practices did not ensure appropriate testing of tissues for infectious organisms prior to transplantation.

We announced our MEDWATCH program, a revamped adverse event reporting system for drugs, biologics and medical devices last June and I'm pleased to say we are already seeing more of the kind of reports we need to monitor the safety of marketed medical products. This is a very important program that will prevent patient suffering, illness, and even death. We also registered some important gains on the international front. A lot of hard work on the part of agency staff has resulted in major strides in international harmonization of drug regulatory requirements. And just a few weeks ago the Administration announced a major agreement with Russia under which drugs and biologics approved by the FDA will be allowed

entry in to the Russian Federation without additional clinical trials and the review period will be limited to a period of 90 days.

The Center for Veterinary Medicine has been involved in several major activities. One is the development of new regulations for phased review of investigational new animal drug applications. The Center is also working on a rewrite of the New Animal Drug Application regulations which will be published this year, and new regulations for generic new animal drugs.

Our National Center for Toxicological Research is developing closer links with the other centers. FDA's Centers are relying on NCTR to undertake risk assessment work, including -- but going beyond -- the traditional focus on carcinogenicity. We are particularly pleased to introduce to the Committee our newest Center Director, Dr. Bernard Schwetz. His leadership will elevate the Centers' role in providing for essential science base for FDA decisions.

On the management side, I am pleased to report that we are making great progress in developing FDA's strategic plan. This is a major initiative which will support our Department's management themes, promote continuous improvement inside FDA and provide a blueprint for

reinventing our regulatory programs. We at FDA are committed to implementing the strategic plan.

Before moving on to the 1995 budget request, I also want to note that in 1993 the Agency issued new guidelines for inclusion of women in clinical trials. This is but one example of the Agency's continuing commitment to address important issues in women's health. Over the next year we will be working with local review boards and sponsors to ensure the effective implementation of these guidelines. In 1994, we are establishing an Office of Women's Health and working to expand our efforts on behalf of women's health.

Finally, let me say that our commitment to enforcing the law remains strong. We have not hesitated to take action against companies -- or individuals -- that are violating laws aimed at ensuring the safety of products we regulate.

These are some of the accomplishments of 1993, and initiatives for 1994. Now let us turn to our 1995 request which we think will strengthen some of our most important programs and functions. Our 1995 request is for \$988 million, \$54 million more than in 1994, all which are additive user fees.

Prescription Drug User Fee Act - Our 1995 budget proposal requests the authority to collect an estimated \$79 million

in user fees, an increase of about \$23 million over 1994, to ensure that the maximum level of resources are available to continue implementation of the Act. We expect the number of full-time equivalent employees for human drugs and biologics programs would increase by 319 by the end of 1995.

With additional resources available we are committed to specific performance goals. From 1994 through 1996, we are to review and act on an escalating percentage of both priority and standard applications. In 1995, 70 percent of new drug applications and product license applications/establishment license application submissions received are to be reviewed within 12 months.

Over the next year we hope to extend user fees to medical devices. During the last few months FDA has been working with our authorizing committees and with medical device industry representatives to consider some important issues: the need for program improvements financed by industry fees; the principles underlying collection and use of user fees; performance goals for FDA; FDA management initiatives to be undertaken; and a preferred fee structure concept. We are hopeful that authorizing legislation for such a program will be enacted soon. It is a very high priority for the agency and the Administration as reflected by the inclusion of \$24 million in additive user fees in the President's budget.

One of the most enterprising sectors of American industry is the manufacture of medical devices. It is a rapidly growing industry -- continually developing a stream of innovative products, and new challenges for the Agency. FDA, we believe, contributes to the success of these manufacturing firms. We do this through our high standards of regulatory oversight ensuring the safety and effectiveness of these medical device products, and thus the long term success of the industry.

However, keeping pace with this industry entails an enormous amount of energy. We must become the efficient and effective gatekeeper to the marketplace, and not a bottleneck to innovation and the marketing of safe and effective medical devices and diagnostic products. These additional resources offer the potential for: strengthening the scientific and underpinnings of review and regulation of medical devices; eliminating the existing backlog of product applications within two years; accelerate review times; improve the quality of clinical trial data submitted by sponsors; and continue implementation of process improvements/guidance to the industry.

Mammography Quality Standards Act user fees -- Our 1995 request continues implementation of the Mammography Quality Standards Act. We propose the collection of \$6.5 million in user fees to fund new inspections to ensure the reliability

of mammography equipment and facilities and mammograms nationwide.

The remaining amount, \$228 million is to come from new user fees that will reduce FDA's reliance on appropriated funds. The Administration believes that it is appropriate for industries that accrue a benefit from FDA's activities to pay for the cost of such activities. FDA's reputation for ensuring that regulated products are safe and effective improves the competitive position of American firms in the global marketplace and enhances consumer confidence in our products.

In summary, our 1995 request includes \$645 million in budget authority and \$343 million from user fees. The user fees include \$79 million from the prescription drug industry; \$24 million from proposed new user fees to be collected from the medical device industry; \$6.5 million from user fees already authorized by the Mammography Quality Standards Act; and \$5 million from fees charged for certification and Freedom of Information Act Services.

Mr. Chairman, Members of the Committee, FDA is doing all we can to protect and promote the public health. This agency remains committed to maintaining its vigor and vigilance on behalf of the American people. We thank you for your support.

This concludes my prepared remarks. My staff and I are here to answer any questions you may have.

DEPARTMENT OF HEALTH AND HUMAN SERVICES



FISCAL YEAR
1995

Volume XII

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

*Justification of
Estimates for
Appropriations Committees*

FOOD AND DRUG ADMINISTRATION

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FOOD AND DRUG ADMINISTRATION BUDGET AUTHORITY BY ACTIVITY

Project Funds	FY 1993 ACTUAL		FY 1994 APPROP		FY 1994 CRNT ESTIMATE		Inc/Dec		FY 1995 ESTIMATE		Inc/Dec	
	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount
	2,695	\$204,060	2,695	\$221,648	2,695	\$221,648			2,550	\$221,648	(145)	
Human Drugs	2,449	211,647	2,520	240,527	2,520	241,710	5/	1,163	2,600	253,721	6/	\$12,011
Biologics	969	98,281	1,040	130,233	3/	131,334	5/	1,101	1,184	142,482	7/	\$11,128
Animal Drugs & Feeds	485	38,017	485	51,833	485	51,833			459	41,653	(26)	
Total, Drugs	3,903	347,945	4,045	412,363	4,045	414,877		2,284	4,223	437,816	178	23,139
Device & Rad Products	1,683	129,025	1,781	153,314	4/	153,314			2,108	163,814	8/	\$30,500
NCTR	257	32,986	257	33,756		33,756			243	33,756	(14)	
Program Management	401	45,432	362	46,228	398	49,012	36	2,784	377	48,973	(21)	(\$39)
Salaries & Expenses:	8,939	780,088	9,140	867,339	9,176	872,407	36	5,068	9,499	926,007	323	53,800
Rental Payments	---	20,066	---	48,575	---	48,575	---	---	---	48,575	---	---
Buildings & Facilities	---	19,664	---	8,350	---	8,350	---	---	---	8,350	---	---
Total Activity:	8,939	805,818	9,140	924,264	9,176	929,332	36	5,068	9,499	982,932	323	53,800
USER FEES:												
DEFICIT USER FEES												
DEVICE												
LESS DPUFA		(8,949)		(54,000)		(56,284)		(2,284)		(24,000)		(\$28,000)
LESS MQSA		---		---		---		---		(79,423)		(\$23,136)
TOTAL USER FEES:		(8,949)		(54,000)		(56,284)		(2,284)		(6,500)		---
										(337,923)	0	(275,139)
S&E BA:												
CRADAS	8,939	\$798,869	9,140	\$870,264	9,176	\$873,048	36	\$2,784	9,499	\$845,009	323	(\$221,339)
Contingency Fund	2	[221]	2	[117]	2	[117]		[-29]	2	[324]		0
Reimbursable	0	0		3,682		3,682		2,284	33	351,703	0	\$281,639
GRADAs (carryover)	39	14,895	4	67,780	8/	70,064		[-45]				
B&F (carryover)				[198]		[198]						
Total S&E Oblig Authority	9,980	\$811,764	9,175	\$960,011	9,211	\$985,079	36	\$5,068	9,534	\$986,712	323	\$60,100
Other Accounts												
Parklawn Computer Ctr	117	---	117	---	117	---	---	---	117	---	0	\$0
Revolving Fund-Cert.	42	3,392	42	4,028	42	4,028	---	---	42	4,187	0	\$141
Total Authority All Accts:	9,139	\$815,156	9,334	\$964,037	9,370	\$989,105	36	\$5,068	9,693	\$1,000,876	323	\$60,241
SCORABLE BUDGET:												
SALARIES & EXPENSES		\$805,818		\$924,264		\$929,332		\$5,068		\$982,932		\$83,900
REVOLVING FUND/FOIA		3,392		4,628		4,826				4,967		141
TOTAL SCORABLE BUDGET:		\$809,210		\$929,090		\$934,158		\$5,068		\$987,899		\$83,741

FOOD AND DRUG ADMINISTRATION BUDGET AUTHORITY BY ACTIVITY

FOOTNOTES:

- 1/ For comparability FY 1993 Actual and FY 1994 Current Estimate includes an OGC transfer of: \$2,616,000 with 39 FTE; and, \$2,784,000 with 36 FTE respectively. FY 1995 includes a transfer of \$2,745,000 and 34 FTE.
- 2/ Includes 90 FTE and \$28,000,000 of the requested \$54,000,000 for PDUFA.
- 3/ Includes 91 FTE and \$26,000,000 of the requested \$54,000,000 for PDUFA and \$10,000,000 for Immunization.
- 4/ Devices includes \$30,000,000: \$20,000,000 and 99 FTE for the Safe Medical Devices Act; and, \$10,000,000 and 30 FTE for Mammography Quality.
- 5/ Human Drugs and Biologics includes an additional \$1,183,000; and, \$1,101,000 respectively for the PDUFA Supplemental of \$2,284,000, bringing the total to \$56,284,000 for PDUFA in 1994.
- 6/ Includes a total of \$41,194,000 and 250 FTE of the requested \$79,423,000 for PDUFA.
- 7/ Includes a total of \$38,229,000 and 250 FTE of the requested \$79,423,000 for PDUFA.
- 8/ Devices includes \$24,000,000 and 246 FTEs for Device User Fees, which will require authorizing legislation from Congress; and \$6,500,000 for MQSA Collections. Additionally, FTEs include a total of 212 FTEs for SMDA; and 61 FTEs for MQSA.

SUMMARY OF CHANGES

(Dollars in thousands)

	<u>FTE</u>		<u>\$000</u>	
1994 Appropriation	9,140	1/	\$924,264	
1994 Proposed Supplemental – PDUFA			2,284	
Comparable OGC Transfer	36		2,784	
1994 Comparable Budget	9176		\$929,332	
(Obligations)			(\$965,394)	2/
1995 Request	9,499		\$982,932	
(Obligations)			(\$997,036)	2/
Net change	323	+	\$53,600	
Obligations		+	(\$31,642)	
	1994 Base		Change from Base	
	<u>FTE</u>		<u>FTE</u>	<u>(\$000)</u>
Increases: Built-in:	9,176		323	
1995 Pay Raise of 1.6% (75%)			+	6,525
Annualization of 1994 locality pay			+	5,328
Within grade increases			+	6,009
Service and Supply fund			+	1,940
Working Capital Fund			+	29
NIH management fund			+	5,555
Other			+	9,829
Subtotal built in inc:				35,215
PDUFA Inc			319 +	23,139
Device User Fees			246 +	24,000
SMDA annualization of FTEs			113	
MQSA			31	6,500
Subtotal User Fee Increases			709	\$53,639
TOTAL INCREASES:				\$88,854
Decreases:				
Net 1995 OGC Transfer			(2) -	(39)
One less day of pay				(1,686)
Program: Absorption of built-in increases & Administrative Reductions			-	(33,529)
FTE Reductions to absorb FTE increases			(384)	
NET CHANGE:			323 +	53,600

1/ Excludes FTEs in Reimbursable, Parklawn Computer Center, Revolving Fund and CRADAs for a total FTE of 9,334 in FY 1994 and 9,693 in FY 1995.

2/ In addition to FY 1994 Appropriations, funding for obligations includes anticipated Reimbursable, and User Fee obligations.

95Congr\Surch.

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FOOD AND DRUG ADMINISTRATION

Highlights of the 1995 Budget Request

In total, the 1995 budget request is \$987,899,000 for the programs of the Food and Drug Administration, including \$645,009,000 in budget authority and \$342,890,000 from collection of user charges. These collections are estimated and presented as follows: \$228,000,000 in user fees assessed on FDA regulated industries; \$79,423,000 from collection of Prescription Drug User Fees; \$24,000,000 in proposed medical device user fees which will support enhancement of device review processes; \$6,500,000 from collection of inspection cost user fees authorized by the Mammography Quality Standards Act (MQSA); and, \$4,967,000 in fees for Certification and Freedom of Information Act services.

In keeping with the President's A Vision of Change for America, FDA's FY 1995 request contains user fee financed increases targeted to promote the health and well being of Americans through the prevention of illness and injury. The program areas which will experience increases include: the medical device review process and other related program areas, and continued enhancements in the human drug and biologic review programs supported by new additional revenues authorized by the Prescription Drug User Fee Act.

The President's Efforts to Reduce the Budget

FDA continues to support the President's efforts to reduce the deficit through the reduction of FTE and other operational costs. In support of these efforts, this budget proposes that FDA absorb estimated pay raise and other inflationary costs.

As evidence of the high priority placed on FDA staffing, FDA is the only PHS agency accorded relief from its FTE target defined by the President's Executive Order to reduce employment. FDA full-time equivalent employment for FY 1995 will be 9,693 of which 746 FTE will be funded by user fee revenue. This level provides significant increases in employment for certain new human drug, biologic, devices, and mammography activities, while FTE's in other FDA program activities will be reduced to absorb pay raise and achieve other administrative cost savings.

Program Initiatives

<u>Prescription Drug User Fees</u>	- \$25,423,000
FY 1994 Supplemental	\$ 2,284,000
FY 1995 Increase	\$23,139,000

This budget includes a request for a supplemental appropriation of \$2,284,000 in FY 1994 user fees authorized under Section 736(c) of the Prescription Drug User Fee Act (PDUFA). Additionally, \$79,423,000 is included in FY 1995 for PDUFA fees.

The Act allows FDA to collect user fees to enhance the processes for review of new human drug and biologic applications. The PDUFA provides FDA with additional resources for expediting the review of applications so that new safe and effective therapies will be available to consumers more quickly. With the availability of the additional resources, FDA committed to specific performance goals. The Act's five-year goal (through FY 1997) is to reduce the review time for priority applications to within six months of submission, and the review time for standard applications to within 12 months of submission. From FY 1994 through FY 1996, FDA is to review and act on an escalating percentage of both priority and standard applications. In FY 1995, 70 percent of NDA and PLA/ELA submissions received are to be reviewed within 12 months.

The Act permits FDA to charge three separate kinds of fees to raise these revenues. A third of the revenues each year will come from each of the following three areas: (1) from product fees assessed on each of the approximately 2,000 listed drug and biologic products; (2) establishment fees to come from each of the approximately 200 manufacturing establishments; and (3) from application fees that must accompany new drug applications and product license applications and supplements with clinical data. Fee amounts and provisions for adjusting these amounts according to inflation are set forth in the Act, and the amounts requested in both 1994 and 1995 are consistent with these adjustment provisions.

Medical Devices User Fees - \$24,000,000

To enhance its ability to ensure the safety and effectiveness of medical devices, FDA is proposing to collect user fees from the medical device industry. FDA has reached significant agreement with the medical device industry on the principles underlying collection of user fees. In the coming months, FDA will work with the industry and the Congress to development medical device user fee legislation.

FDA will use the proposed medical device user fees to virtually eliminate application backlogs within two years for Premarket Notifications (510(k)s), Premarket Approval Applications (PMAs) and PMA supplements; review and act on device applications within accelerated timeframes; facilitate the expedited review process through increased guidance to industry; strengthen postmarket monitoring and management capabilities to improve our ability to assess, public health risks; and upgrade automation capabilities and integrate program information systems.

Mammography Quality Standards Act Collections - \$6,500,000

The FY 1995 budget continues implementation of the Mammography Quality Standards Act of 1992 to ensure that mammograms are properly performed and interpreted. Beginning in 1995, certified personnel will begin inspecting mammography facilities to ensure

that facilities comply with uniform Federal standards. The 1995 budget allows FDA to collect user fees, as authorized by the Mammography Quality Standards Act, to capitalize funding of mammography inspection activities for the future.

Additional User Fees - \$228,000,000

In addition to the Prescription Drug User Fees, Medical Device User Fees and Mammography user fee collections, the budget proposes the collection of \$228,000,000 in new user fees to be derived from FDA regulated entities. The budget envisions that these fees will be collected to offset base costs of FDA's ongoing operations, and that they will be credited to FDA's appropriation.

The industries regulated by FDA derive valuable benefits from some FDA activities, including consumer confidence in their products and significant protection from liability. FDA's reputation also improves the competitive position of American firms in the global marketplace. The Administration believes that it is appropriate for industries that accrue a benefit from FDA's activities to pay for the cost of these activities. Accordingly, FDA's budget proposes a savings of \$228,000,000 in budget authority.

General Counsel Transfer - \$2,745,000 and 34 FTE

The budget proposes that the resources to support the Food and Drug Division of the Office of General Counsel, Office of the Secretary, Department of Health and Human Services, be included in the appropriation for the Food and Drug Administration in FY 1995 and future years, and that the function become a part of FDA's organization. The transfer is being requested for two reasons: 1) The expansion of FDA's program goals and objectives which have generated an increased demand for certain legal services; and 2) OGC and FDA are launching a pilot program in FDA to test the efficacy of decentralizing the provision of departmental legal services.

For comparability, 1993 actuals and the 1994 comparable column of the budget reflect transfers of \$2,616,000 and 39 FTE; and, \$2,784,000 and 36 FTE, respectively. The transfer is resource neutral; offsetting reductions are proposed in the FTE and dollars in the Office of the Secretary's budget.

APPROPRIATIONS LANGUAGE

Salaries and Expenses

For necessary expenses of the Food and Drug Administration, including hire and purchase of passenger motor vehicles; for rental of special purpose space in the District of Columbia or elsewhere; and for miscellaneous and emergency expenses of enforcement activities, authorized and approved by the Secretary and to be accounted for solely on the Secretary's certificate, not to exceed \$25,000; [\$867,339,000, of which not to exceed \$54,000,000 in fees pursuant to section 736 of the Federal Food, Drug, and Cosmetic Act may be credited to this appropriation and remain available until expended: Provided, That fees derived from applications received during fiscal year 1994 shall be subject to the fiscal year 1994 limitation: Provided further, That none of these funds shall be used to develop, establish, or operate any program of user fees authorized by 31 U.S.C. 9701: Provided further, That none of the funds in this Act may be used to pay for expenses of the Board of Experts on Tea] \$588,084,000; including such sums as necessary for the inspection of mammography facilities, notwithstanding section 354(r) of the Public Health Service Act; and in addition, \$252,000,000, to be credited to this appropriation, from fees established and collected to cover the costs of regulation of products under the jurisdiction of the Food and Drug Administration, to remain available until expended.

In addition, fees pursuant to section 736 of the Federal Food, Drug, and Cosmetic Act may be credited to this appropriation and remain available until expended in accordance with section 736(g) of such Act: Provided, That the amount of such fees may be adjusted pursuant to section 736(c) of that Act: Provided further, That fees derived from applications received during fiscal year 1995 shall be subject to the fiscal year 1995 limitation.

In addition, fees pursuant to section 354 of the Public Health Service Act may be collected and credited to this account, to remain available until expended. (Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1994.)

Rental Payments (FDA)
(Including Transfers of Funds)

For payment of space rental and related costs pursuant to Public Law 92-313 for programs and activities of the Food and Drug Administration which are included in this Act, \$48,575,000 [, of which \$15,000,000 shall be retained by the Food and Drug Administration for repairs, improvements, and non-recurring repairs as determined by the Food and Drug Administration]: Provided, That in the event the Food and Drug Administration should require modification of space needs, a share of the salaries and expenses appropriation may be transferred to this appropriation, or a share of this appropriation may be transferred to the salaries and expenses appropriation, but such transfers shall not exceed 5 per centum of the funds made available for rental payments (FDA) to or from this account. (Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1994.)

Buildings and Facilities

For plans, construction, repair, improvement, extension, alteration, and purchase of fixed equipment or facilities of or used by the Food and Drug Administration, where not otherwise provided, \$8,350,000, to remain available until expended (7 U.S.C. 2209b): Provided, That the Food and Drug Administration may accept donated land in Montgomery and/or Prince George's Counties, Maryland.
 (Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1994.)

[FY 1994 SUPPLEMENTAL]

FOOD AND DRUG ADMINISTRATION

Salaries and Expenses

(Supplemental now requested; existing legislation)

For an additional amount for "Salaries and Expenses" from fees collected pursuant to section 735 of the Federal Food, Drug, and Cosmetic Act, not to exceed \$2,284,000, to remain available until expended: Provided, That fees derived from applications received during fiscal year 1994 shall be credited to the appropriation current in the year in which the fees are collected and subject to the FY 1994 limitation.

STATEMENT OF PURPOSE

The Food and Drug Administration (FDA) is the principal consumer protection agency of the Federal Government. FDA's goal is to see that consumer confidence is warranted by ensuring industry's compliance with Federal laws regulating products in commerce.

The laws that provide FDA's authority are intended to ensure that: (1) food is safe and wholesome; (2) drugs (both human and veterinary), biological products (e.g., vaccines and blood for transfusion), and medical devices are safe and effective; (3) cosmetics are unadulterated; (4) the use of radiological products does not result in unnecessary exposure to radiation; and (5) all of these products are honestly and informatively labeled.

The major operations of the Food and Drug Administration reflect the strategies inherent in the laws the Agency enforces. These strategies are (1) to identify health problems associated with FDA-regulated products and assess their origin and impact; (2) to grant pre-market approval only to products meeting legal and regulatory standards; (3) to make every effort to prevent problems which would expose the public to hazards; (4) to monitor the marketplace to ensure compliance with the laws and regulations; (5) to correct problems in the development and distribution of products; and (6) to punish violators when appropriate. The laws enforced by FDA provide the legal means to accomplish these goals.

Pre-Market Clearance

The law requires that many health-related products undergo rigorous testing before being offered for sale. It is FDA's job to review manufacturers' testing methods and test results. The general nature of the test procedure and FDA's review is prescribed by the statutes but varies with the type of product and the potential hazard associated with it.

For most of the products it regulates, FDA also prescribes standards for research laboratory practices and for manufacturing practices.

Monitoring: Inspections, Investigations, Surveillance

The law recognizes the need to continuously monitor the marketplace constantly. The statutes provide FDA the authority to inspect establishments, examine samples, and conduct investigations to ensure that product quality standards are being met at every stage

of the commercial system: research and development, production, storage, and distribution. Many potential hazards can thus be identified and corrected in time to prevent or minimize public exposure. FDA's field operations, inspect domestic establishments and analyzing product samples, are an excellent means of monitoring the marketplace.

Compliance Activities: Correction and Penalties

Firms must correct problems identified by FDA inspectors. Except when a violation is intentional or flagrant, or constitutes a danger to health, the management of a firm is given the opportunity to correct the violation voluntarily before FDA pursues regulatory action. Less severe problems can sometimes be corrected by "reconditioning" the product--for example, replacing violative labeling with acceptable labeling. FDA can also encourage a company to recall a violative product, or request a company to modify unsafe manufacturing processes. If necessary, the Agency can cause a violative product to be destroyed, and/or broadcast public warnings about it.

The law acknowledges that it is sometimes necessary to punish violators, thereby deterring similar occurrences in the future. The Act provides for criminal prosecution that can lead to fines or imprisonment. A Federal court can also order seizure of a product or issue an injunction forbidding an establishment's operations for some period of time.

Promulgation of Regulations

Regulations are a basic tool for achieving FDA's goal of consumer protection. FDA's regulations inform the affected industries and public of statutory requirements and the Agency's procedures; they interpret the law and spell out the details needed to implement the general provisions in the statutes. Regulations also describe the approval processes for many individual products or set forth required standards of product composition or performance. Most FDA regulations have the force and effect of law.

**SIGNIFICANT ITEMS IN APPROPRIATIONS
COMMITTEE REPORTS**

Fiscal 1994 House Report No.
103-153

Actions Taken or to be Taken

User Fees

"The Committee continues to express its belief that user fees for the Food and Drug Administration are such a significant policy change that the Department of Health and Human Services should work with the appropriate Committees of Congress to have them specifically authorized."

The Administration continues to believe that the regulated industries that benefit from FDA operations should share in the cost of ensuring the safety and effectiveness of their products. FDA agrees that user fees are a significant policy change for the Agency. However, while FDA agrees that specific legislative authority for user fees is often desirable, it is not necessary in all areas. FDA is willing to work with the appropriate Committees of Congress to have user fees authorized. In the past, the Agency worked extensively with the Congress, as well as the drug industry, on the authorization of the Prescription Drug User Fee Act of 1992 which is to provide the Agency with the additional resources to significantly expedite the drug approval process. This Act set a precedent in the area of user fees for the Agency.

Staffing Levels

"The Committee is concerned that adequate staffing levels for development of and inspection activities related to compliance with the Mammography Quality Standards Act be achieved. Within the overall increase for FDA staffing, the Committee expects that increases in FTEs be made available to comply with the requirements of the Act."

The FY 1993 Supplemental Appropriation provided \$3,000,000, the first funding specifically designated to initiate implementation of the Mammography Quality Standards Act. The FY 1994 budget provided \$13,000,000 for implementation of the Mammography Quality Standards Act which allows FDA to bring on a total of 65 staff to support this program. The majority of the additional staff will be used for regulation development, planning for and conducting the inspector training, initial certification of an estimated 10,000 facilities, and development of compliance and enforcement procedures. In accordance with the statute, which requires State involvement where feasible in the inspection program, FDA's implementation plans assume significant State participation in the program, with the bulk of initial inspections and re-inspections performed by State personnel.

Imported Tea

"Current statutory language requires there be a Board of Experts on Tea. This is part of the requirement of the Tea Import Act originally enacted in 1897. The Board is established to annually set standards for imported tea. Currently, it requires importers to pay 3.5 cents for each hundredweight of imported tea. The fee was set to offset the costs of the Board-of-Experts and inspection activities. The fee was last revised in 1940 and no longer covers the entire cost. Since the Board's activities generally are for the benefit of the tea industry, the Committee believes the industry should work with Congress to set a fee that fully covers the costs. The Committee has provided language prohibiting expenses of the Board of Experts on Tea from receiving appropriated funds for expenses."

In conformance with the provisions of P.L. 103-111, during 1994, FDA will not use any appropriated funds to operate the Board of Tea Experts. Industry members now participate at their own expense. The fee charged importers has been increased from 3.5 cents to 10 cents per hundredweight of tea examined. The increase was effected through an amendment to the Tea Importation Act under the Omnibus Budget Reconciliation Act of 1993. The revenue is intended to offset the direct costs incurred by FDA for its participation in this activity.

Border Inspections

"The Committee expects FDA to increase border inspection personnel along the U.S./Mexico border."

In Fiscal Year 1994, FDA has assigned five additional staff to the regions bordering Mexico for Electronic Entry Review and import operations. The Electronic Entry Review is the new integrated interface and internal processing system for imports which is part of a joint project with the U.S. Customs Service. This is FDA's groundwork for a long-term interface with Customs that will provide uniformity and higher level processing within FDA, as well as provide short-term processing capabilities. FDA and Customs are embarking on new methods of electronic data interchange in an effort to be more customer oriented and to relieve the private sector of the burden of unnecessary paperwork.

Fiscal 1994 Senate Report
No. 103-102

Medical Devices

"The Committee has been concerned about the inability of FDA to approve safe and effective, new medical devices promptly. Advances in new technology, which can save lives or ameliorate suffering, have not been available to the American patient population due to the regulatory logjam in the approval process. Further, many device manufacturers are moving their developmental activities abroad in order to avoid delays created by inappropriate approaches to regulation. The announcement by the new director of the Center for Devices and Radiological Health of several initiatives to establish better defined priorities and expedited reviews is a first step in addressing this problem. It is critical that the director be given full support in implementing these reforms and that additional steps be taken to streamline or eliminate requirements in the approval process which create inordinate delays in getting products to people and do not contribute to ensuring safety and efficacy. The Committee will closely monitor this situation and hopes to see an increased number of device approvals and shortened timetables for product reviews."

In FY 1993, FDA initiated a new four-pronged strategy for increasing the efficiency and scientific rigor of the device review program: (1) expedited review policy to establish a separate review queue for innovative devices with life-saving and/or superior clinical benefits; (2) refuse to accept/file policy which permits FDA to reject applications that are incomplete and/or contain inadequate data; (3) risk-based approach that allocates review assignments according to product complexity and risk potential; and (4) premarket notification status information program designed to respond quickly (within 3 days) to manufacturers' requests for information about their applications.

FDA is trying to reduce the product review backlog. During the last six months of 1993, FDA stabilized the backlog of premarket notifications by issuing 151 more final decisions than receipts. In FY 1993, FDA approved 24 premarket approval (PMA) applications, (twice as many as last year).

From increases provided in 1994, FDA is adding approximately 220 additional staff to support the device review process and to more fully implement significant portions of the Safe Medical Devices Act of 1990.

Prescription Drug Prices

"The Committee is concerned about escalating prescription drug prices, which has led to consideration of proposals for cost controls. The Committee recognizes that generic drug competition can play a significant role in keeping prices down, and encourages FDA to support the development and approval of generic drugs consistent with the Waxman-Hatch Act."

FDA is continually searching for ways to support the development and approval of safe and effective generic drug products. The number of generic drug applications is increasing. The Agency's productivity initiatives have succeeded in significantly reducing the backlog of overdue generic drug applications. Faster approval of generic drug applications should increase drug competition and help to slow the escalation in prescription drug prices.

In addition, the Agency is trying to improve technical guidance to industry. Such efforts include the conduct of industry and advisory committee meetings on scientific and regulatory issues related to generic drugs and preparation of guidance documents, particularly on bioequivalence requirements for various types prescription drugs. These activities should help remove some of the scientific and regulatory hurdles facing the industry and facilitate the preparation of generic drug applications.

Bottled Water

"The Committee recognizes that approximately 1 out of every 15 households currently consumes bottled drinking water. Despite comprehensive FDA and State regulation of the quality and safety of bottled water, specific gaps have developed in the Federal regulation of bottled water. The Committee is pleased that earlier this year FDA proposed new quality standards and definitions for bottled water and thereby increase consumer confidence when purchasing bottled water. The Committee urges FDA to finalize these proposals as quickly as it is feasible to do so. The Committee also recognizes the FDA has a memorandum of understanding with the Environmental Protection Agency (EPA) on setting quality standards for bottled water. In some cases, the industry has adopted more stringent standards than those set by EPA. The Committee hopes that in the future, when quality standards are set by EPA, FDA will move expeditiously to adopt appropriate standards for bottled water."

FDA has made significant progress in developing regulations for bottled water. During 1993, FDA published in the Federal Register one final rule and five proposed rules on the regulation of bottled water. The final rule established maximum allowable levels for 7 volatile organic chemicals (e.g., benzene); the four proposed rules were to establish or revise maximum allowable levels for 65 additional chemical contaminants (e.g., lead) for total coliform bacteria in the quality standard for bottled water. In addition, FDA proposed to establish an identity standard for bottled water that would define various types of water (artesian, distilled, purified, spring, and well) that are bottled and to make mineral water subject to the bottled water quality standard.

With these publications, FDA has caught up with EPA's promulgation of National Primary Drinking Water Regulations (NPDWR's) in accordance with section 410 of the Food, Drug, and Cosmetic Act. FDA is currently developing final rules based on these five proposed rules and expects to publish them in the Federal Register during 1994. Moreover, in accordance with section 410 of the Act, FDA anticipates that it will continue to amend the quality standard for bottled water in a timely manner in response to EPA's promulgation of NPDWR's.

Clinical Trials/Women

"The Committee is disappointed that FDA's drug, device, and biologics testing policy excludes women. The Committee is aware of a recent GAO study which found that women continue to be underrepresented in clinical trials for new drugs, fewer than one-half of new drugs are analyzed for gender-related effects, and differences in the way men and women respond to drugs has not received adequate study. The Committee also recognizes that FDA expects to issue revised clinical trial guidelines which are more equitable to women. In light of the GAO report and FDA's current efforts, the Committee recommends that \$2,000,000 be used to expand and strengthen FDA's infrastructure with regard to women's health by establishing an Office of Women's Health in the Office of the Commissioner. The Committee expects that the FDA Office of Women's Health will work to correct gender disparities in FDA drug, device, biologics testing and regulation policy, oversee the implementation of the revised clinical trial guidelines with respect to the representation of women, and coordinate FDA Women's health policy with the PHS Office of Women's Health and other PHS agency offices of women's health as appropriate."

FDA is taking action to formally establish an Office of Women's Health in the Office of the Commissioner. Generally, the functions of the new office have been carried out by the Special Assistant to the Commissioner for Women's Health Issues in collaboration with FDA's Office of External Affairs (OEA) and relevant FDA Centers. FDA's senior management is focused on addressing in the short term: (1) refinement and development of initiatives to ensure that women's health issues are routinely addressed in all Agency undertakings; (2) improvement of Agency-wide awareness and coordination of specific women's health activities underway within FDA; and (3) development of a plan that will identify the highest priority needs for women's health and specific Agency proactive initiatives to address such needs.

Once established, the Office will: continue to provide policy advice and alternatives to the Commissioner and other Agency managers regarding issues of women's health; strive to insure that all functions, regulatory and oversight, are gender sensitive, coordinated and responsive to women's health needs; work with other Agency organizations to identify and to correct gender disparities in drug, device, and biologics testing and regulation policy; and monitor the implementation of the revised clinical trial

guidelines to ensure that women are represented adequately in clinical trials and that gender analyses are included routinely in product applications.

DESCRIPTION OF FIELD ACTIVITIES

FDA's field workforce, which comprises nearly 40 percent of FDA's total staffing, performs inspections, sample collections and analyses, and initiates enforcement actions. In addition to conducting regular surveillance over regulated products, this workforce also serves a critical response function when the Agency must respond to crises by immediately mobilizing to investigate reports of product problems and tampering incidents. The field is involved in informing businesses and consumers about FDA-related topics, and in working with State and local agencies to develop programs that make the best use of Federal, State, and local resources in protecting the public health. The field workforce also screens, examines, and collects samples from all regulated products imported into the U.S.

FDA's field force conducts investigational and laboratory functions for all of FDA's major product areas--Foods, Human Drugs, Biologics, Animal Drugs and Feeds, and Medical Devices and Radiological Products. With a highly-trained staff versed in all of FDA's product responsibilities, the Agency can respond rapidly to various types of emergencies, and can also redirect field efforts from time to time during the year among FDA's different programs, as inspection and product testing needs change.

To complement the regular field force the Office of Criminal Investigations was established during FY 1992 as part of our efforts to more effectively investigate instances of criminal activity in the regulated industries. The agents have been given intensive training at the Federal Law Enforcement Training Center in Glevco, Georgia. They are located in six field offices in Metro Washington, Chicago, New York, Kansas City, Miami, and San Diego.

Field facilities include Regional Offices, District Offices, laboratories, and resident posts. The six Regional Offices are staff offices which coordinate FDA activities, and also coordinate with state authorities. The 21 District Offices serve as offices for investigators and compliance action staff, and are the main control point for day-to-day operations in their assigned areas. The 18 District Laboratories provide FDA's basic field product testing capability. In addition, a number of these laboratories serve as specialized facilities for certain important types of testing and research.

In addition to these facilities, FDA maintains over 130 resident posts distributed widely throughout the nation. These are smaller offices which serve primarily as a base for investigators, so that FDA can have investigative staff widely dispersed to respond to emergencies, as well as to save inspectional travel costs and time.

With all of these Field facilities combined, FDA maintains offices and staff in 49 of the States, and in the District of Columbia and Puerto Rico. (List of FDA facilities follows.)

GEOGRAPHICAL DISTRIBUTION OF FDA FACILITIES

<u>Location</u>	<u>Activities</u>
Washington, D.C. area: Rockville, MD	FDA Headquarters and headquarters operations of the Drugs, Devices & Radiological Products programs, and Device & Radiological laboratories
Washington, D.C.	Foods program headquarters and laboratories
Bethesda, MD	Human Drugs and Biologics laboratories
Rockville, MD	Medical Device program offices
Beltsville, MD	Foods and Veterinary Medical research facilities
Field Operations Facilities:	
Stoneham, MA	District Office
Brooklyn, NY	Regional Office, Regional laboratory and District Office
Buffalo, NY	District Office and laboratory
San Juan, PR	District Office and laboratory
West Orange, NJ	District Office
Philadelphia, PA	Regional Office, District Office and laboratory
Baltimore, MD	District Office and laboratory
Nashville, TN	District Office
Orlando, FL	District Office
Atlanta, GA	Regional Office, Regional laboratory, and District Office
Chicago, IL	Regional Office, District Office and laboratory
Cincinnati, OH	District Office and laboratory and National Forensic Chemistry Center (elemental analysis)
Detroit, MI	District Office and laboratory (special emphasis in pesticide and industrial chemical testing)
Minneapolis, MN	District Office and laboratory (special emphasis in microbiological testing)
Dallas, TX	Regional Office, District Office, and laboratory
New Orleans, LA	District Office and laboratory (special emphasis in natural toxins testing)
Kansas City, MO	District Office and laboratory (special emphasis in total diet analysis)
Denver, CO	District Office and laboratory (special emphasis in animal drug residue testing)

<u>Location</u>	<u>Activities</u>
San Francisco, CA	Regional Office, District Office, and laboratory
Los Angeles, CA	District Office and laboratory
Seattle, WA	District Office and laboratory (special emphasis in seafood products testing)
Other Specialized facilities:	
Jefferson, AR	National Center for Toxicological Research
Cincinnati, OH	Foods research laboratory in food technology and microbiology (CFSAN)
St. Louis, MO	Specialized human drug product testing laboratory (CDER)
Dauphin Island, AL	Fishery research (CFSAN)
North Kingstown, RI	Specialized facility for shellfish field surveys (CFSAN)
Winchester, MA	Winchester Engineering and Analytical Center (testing of medical devices and radiological products) - also provides general laboratory services to Stoneham, MA District Office

TOTAL RESOURCES AVAILABLE

	1993 Actual		1994 Estimate		1995 Estimate	
	\$000	FTE	\$000	FTE	\$000	FTE
Salaries and Expenses 1/	\$760,088	8,939	\$872,407	9,146	\$926,007	9,499
GSA Rental Payments	26,066		48,575		48,575	
Buildings and Facilities	19,664	---	8,350	---	8,350	---
SUBTOTAL, DIRECT	\$805,818	8,939	\$929,332	9,146	\$982,932	9,499
CRADAS 2/	[221]	2	[315]	2	[324]	2
B&F Carryover			18,285			
Contingency Fund	---		3,682			
Advances and Reimbursements	5,946	39	13,780	33	13,780	33
Parklawn Computer Center 3/	---	117	---	117	---	117
Revolving Fund for Certification and Other Services 4/	<u>3,392</u>	<u>42</u>	<u>4,026</u>	<u>42</u>	<u>4,167</u>	<u>42</u>
TOTAL RESOURCES :	\$815,156	9,139	\$969,105	9,340	\$1,000,879	9,693

Salaries and Expenses contains all User Fees for FY 1993, FY 1994 FY 1995 which includes PDUFA - \$8,949,000 actuals in FY 1993, (\$36,000,000 was appropriated in 1993); \$56,284,000 in FY 1994 and \$79,423 in FY 1995. Additionally, FY 1995 includes Device User Fees of \$24,000,000; Deficit User Fees of \$228,000,000 and MQSA collections \$228,000,000 and MQSA Collections of \$6,500,000.

- 1/ For comparability, FY 1993 and FY 1994 includes an OGC transfer of \$2,616,000 and 39 FTE in FY 1993; \$2,784,000 and 36 FTE in FY 1994. FY 1995 includes an OGC transfer of \$2,735,000 and 34 FTE in FY 1995.
- 2/ Reflects funds under the existing Cooperative Research and Development Agreements. These funds will be used in accordance with the Federal Technology Transfer Act of 1986 (P.L. 99-502) and the Delegation of Authority of February 4, 1988, from the Assistant Secretary for Health to the PHS agency heads.
- 3/ Personnel within the Parklawn Computer Center are administratively assigned to FDA. However, the Center is financed through a revolving fund which is supported entirely by charges for services to the agencies using the Center.
- 4/ FDA certifies batches of insulin and of color additives used in foods, drugs, medical devices, and cosmetics. These services are financed wholly from fees paid by the industries affected.

95 Congr\TotalRes

AUTHORIZING LEGISLATION

(Dollars in thousands)

	<u>1993 Actual</u>	<u>1994 Current Estimate</u>	<u>1995 Estimate</u>
Authorizing Legislation:			
Federal Food, Drug and Cosmetic Act	\$709,714	\$814,757	\$861,857
Fair Packaging and Labeling Act	131	135	135
Import Milk Act	5	7	7
Import Tea Act	194	200	200
Public Health Service Act	<u>95,774</u>	<u>114,233</u>	<u>120,733</u>
	\$805,818	\$929,332	\$982,932

95CONGR\AUTHLEG

Budget Authority by Object Class

(in thousands of dollars)

	1993	1994	Increase or	1994	1995	Increase or
	Actual	Appr.	Decrease	Current Estimate	Estimate	Decrease
11.1 Full-time permanent	\$378,055	\$409,521	\$2,283	\$411,804	\$437,137	\$25,333
11.3 Other than full-time perm	24,523	27,302	---	27,302	29,142	1,840
11.5 Other personnel comp	14,689	16,059	---	16,059	17,149	1,090
11.8 Special personal svcs pay	<u>292</u>	<u>322</u>	---	<u>322</u>	<u>336</u>	<u>14</u>
11.9 Total personnel comp	\$417,559	\$453,204	\$2,283	\$455,487	\$483,764	\$28,277
12.1 Civilian persnl benefits	87,722	92,826	501	93,327	99,084	5,757
13.0 Benefits former personnel	---	---	---	---	---	---
TOTAL PAY & BENEFITS	\$505,281	\$546,030	\$2,784	\$548,814	\$582,848	\$34,034
21.0 Travel & transp of person	\$19,278	\$22,382	\$0	\$22,382	\$21,479	(\$903)
22.0 Transportation of things	1,336	2,340		2,340	2,694	354
23.1 Rent payments to GSA	26,066	48,575		48,575	48,575	
23.2 Rent payments to others	5,409	8,208		8,208	10,626	2,418
23.3 Communications, utilities & miscellaneous charges	22,104	25,882		25,882	28,166	2,284
24.0 Printing & reproduction	3,507	4,460		4,460	4,865	405
25.1 Consulting Services	4,783	5,149		5,149	5,355	206
25.2 Other services	41,941	58,645	2,284	60,929	71,190	10,261
25.3 Purchases of Goods & Services from Government Accounts	36,603	39,376		39,376	38,145	(1,231)
25.4 Operation of GOCOs	15,228	23,612		23,612	22,854	(758)
25.5 Research & Development Contracts	31,111	33,460		33,460	35,915	2,455
26.0 Supplies & materials	25,836	31,490		31,490	34,896	3,406
31.0 Equipment	33,947	56,281		56,281	53,248	(3,033)
32.0 Land & structure	14,327	---		---	3,146	3,146
41.0 Grants, subsidies, & Contributions	16,834	17,000		17,000	17,550	550
42.0 Ins claims & indemnities	<u>2,227</u>	<u>1,374</u>		<u>1,374</u>	<u>1,380</u>	<u>6</u>
99.0 Subtotal	\$805,818	\$924,264	\$5,068	\$929,332	\$982,932	\$53,600
PDUFA	(8,949)	(54,000)		(56,284)	(79,423)	(23,139)
DEFICIT USER FEES					(228,000)	(228,000)
DEVICE USER FEES					(24,000)	(24,000)
MQSA COLLECTIONS	---	---	---	---	(6,500)	(6,500)
Subtotal Direct	\$796,869	\$870,264	\$2,784	\$873,048	\$645,009	(\$228,039)
Contingency Fund	---	---	---	---	---	---
CRADAS	<u>[221]</u>	<u>[117]</u>		<u>[117]</u>	<u>[324]</u>	<u>[207]</u>
Total Direct	\$796,869	\$870,264	2,784	\$873,048	\$645,009	(\$228,039)
99.0 Reimbursable obligations	14,895	67,780	2,284	70,064	351,703	281,639
Carry Over:						
Contingency		3,682		3,682		
CRADAS		[198]		[198]		
Buildings & Facilities		18,285		18,285		
99.9 Total obligations	\$811,764	\$960,011	5068	\$965,079	\$996,712	\$33,600

95CONGR/OCCONGR

DETAIL OF FTE

	<u>1993 Actual</u>	<u>1994 Current Estimate</u>	<u>1995 Estimate</u>	<u>Increase or Decrease</u>
Full-time equivalent employment	8,900	9,176	9,499	323
Full-time equivalent of overtime & holiday hrs.	86	119	119	
Average SES Salary *	\$103,787	\$107,108	\$108,393	\$1,285
Average GS grade	11	11	11	
Average GS salary	\$37,743	\$39,340	\$40,403	\$1,063

* These figures do NOT include benefits.

FIVE YEAR HISTORY OF GS/GM AVERAGE GRADE

<u>YEAR</u>	<u>GRADE</u>
FY 1990	10.22
FY 1991	10.34
FY 1992	10.52
FY 1993	10.78
FY 1994	10.83
FY 1995	10.90

95CONGR\DETAILFTE

FOOD AND DRUG ADMINISTRATION AMOUNTS AVAILABLE FOR OBLIGATION

(Dollars in thousands)

	1993	1994	1994	1995
	<u>Actual</u>	<u>Approp.</u>	<u>Current</u> <u>Estimate</u>	<u>Estimate</u>
Appropriation:				
Annual	\$803,202	\$884,264	\$886,548	\$980,187
Reappropriation				
Transfer	2616		2,784	2745
Supplemental				
Administrative Reductions				
Investment initiatives		40,000	40,000	
Subtotal adjusted	---	---	---	---
appropriation	\$805,818	\$924,264	\$929,332	\$982,932
Offsetting collections				
from:				
Non Federal Sources	(8,949) 1/	(54,000)	(56,284)	(168,423)
CRADAs		(198)		
Buildings & Facilities				
GSA Rent				
Unobligated balance start				
of year	(33,550)	42,480	(20,315)	(42,308)
Unobligated balance end of				
year	42,480	(20,315)	42,308	42,308
Unobligated balance lapsing	58			
Reimbursable	<u>5,907</u>	<u>67,780</u>	<u>70,064</u>	<u>182,203</u>
Total Obligations	\$811,764	\$960,011	\$965,079	\$996,712

1/ FDA received an appropriation of \$36 million for PDUFA in 1993. In FY 1993
FDA collected \$29.3 million, obligated \$8.9 million and is carrying over \$20.3 million.

94Congr\Oblig.

TABLE OF ESTIMATES AND APPROPRIATIONS

(Combines Amounts for Salaries and Expenses and Rental Payments to GSA Appropriations, But Does Not Include Buildings and Facilities Appropriation)

Year	Budget Estimate To Congress	House Allowance	Senate Allowance	Appropriation 1/
1985	392,554,000	394,262,000	398,144,000	409,694,000
1986	417,400,000	418,258,000	425,517,000	420,306,000 <u>2/</u>
1987	453,575,000 <u>3/</u>	435,167,000	436,430,000	436,430,000
1988	488,604,000 <u>4/</u>	476,116,000	488,604,000	476,116,000
1989	507,456,000 <u>5/</u>	502,381,000	494,755,000	507,456,000 <u>6/</u>
1990	582,183,000 <u>7/</u>	575,783,000	607,483,000	592,691,000 <u>8/</u>
1991	680,420,000 <u>9/</u>	680,420,000	687,264,000	682,131,000 <u>10/</u>
1992	760,216,000 <u>11/</u>	751,574,000	730,316,000	751,574,000
1993	782,650,000 <u>12/</u>	769,747,000	769,747,000	817,647,000 <u>13/</u>
1994	915,914,000 <u>14/</u>	915,914,000	740,914,000	915,914,000 <u>15/</u>
1995	974,582,000 <u>16/</u>			

- 1/ Rental Payments to GSA (formerly Standard Level User Charges) included in final Appropriations each year are: \$18,942,000 in 1983; \$22,164,000 in 1984; \$26,072,000 in 1985; \$25,888,000 in 1986; \$24,627,000 in 1987; and, \$25,612,000 in 1988, 1989, 1990, 1991, 1992, and 1993. FY 1994 and FY 1995 includes \$48,575,000.
- 2/ Includes \$18,073,000 which was subsequently sequestered.
- 3/ Includes Amendments of \$5,625,000 and \$25,800,000 proposed to be available from user fees.
- 4/ Includes Amendments of +\$8,880,000 for AIDS, -\$2,357,000 for reduced FERS Agency contribution rate, and \$33,800,000 proposed to be available from user fees.
- 5/ Includes funding of \$40,420,000 for AIDS-related work which was proposed to be funded in the AIDS Research and Education Account.
- 6/ Does not include \$5,000,000 added in the Anti-Drug Abuse Act.
- 7/ Includes \$56,941,000 which was included in the proposed National HIV Program account, \$13,900,000 requested as a supplemental appropriation, and \$100,000,000 proposed to be available from user fees.
- 8/ Includes \$7,092,000 which was subsequently sequestered.
- 9/ Includes \$157,175,000 proposed to be available from user fees.

- 10/ Includes \$8,868 which was subsequently sequestered.
- 11/ Includes \$197,500,000 proposed to be available from user fees.
- 12/ Includes \$200,000,000 proposed to be available from user fees, and \$25,612,000 requested for Rental Payments to GSA.
- 13/ Includes \$1,900,000 to fund a clinical pharmacology pilot program; and a \$3,000,000 supplemental for Mammography Quality Standards Act (MQSA) to be transferred from HCFA, NIH and CDC; and \$36,000,000 for the Prescription Drug User Fee Act.
- 14/ Includes \$54,000,000 for the Prescription Drug User Fee Act (PDUFA); \$64,600,000 for Investment Initiatives; \$200,000,000 proposed to be available from User Fees; and \$48,575 for rental payments to GSA (an increase of \$22,963).
- 15/ Appropriation includes \$54,000,000 for PDUFA; \$40,000,00 for Investment Initiatives and \$48,575,000 in rental payments to GSA.
- 16/ The 1995 request includes \$79,423,000 for PDUFA including a FY 1994 supplemental for PDUFA of \$2,284,000; \$24,000,000 for Device User Fees; \$6,500,000 for MQSA collections; other user fees of \$228,000,000; and \$48,575,000 in rental payments to GSA. Also included is a transfer from Office of the Secretary, Office of General Counsel to FDA of \$2,745,000 and 34 FTE.

TABLE OF ESTIMATES AND APPROPRIATIONS
(Buildings and Facilities Appropriation)

<u>Year</u>	<u>Budget Estimate To Congress</u>	<u>House Allowance</u>	<u>Senate Allowance</u>	<u>Appropriation</u>
1985	1,450,000 <u>1/</u>	1,435,000	1,450,000	1,450,000
1986	1,450,000 <u>1/</u>	1,450,000	1,450,000	1,441,000 <u>2/</u>
1987	1,450,000 <u>1/</u>	1,879,000	1,879,000	1,879,000
1988	1,450,000 <u>1/</u>	1,450,000	1,450,000	1,450,000
1989	26,450,000 <u>1/</u>	23,710,000	25,736,000	23,950,000
1990	1,450,000 <u>1/</u>	6,950,000	12,250,000	8,350,000
1991	4,752,000 <u>1/</u>	8,350,000	10,850,000	8,350,000
1992	10,000,000 <u>1/</u>	10,400,000	8,350,000	8,350,000 <u>3/</u>
1993	8,350,000	8,350,000	8,350,000	8,350,000
1994	8,350,000 <u>4/</u>	8,350,000	8,350,000	8,350,000
1995	8,350,000 <u>5/</u>			

- 1/ Funding of facilities projects - 1984 through 1992 - was included in the Program Expenses request but appropriated in this account.
- 2/ Appropriated amount includes \$62,000 which was subsequently sequestered.
- 3/ Does not include \$200,000,000 provided to GSA in the Treasury, Postal Service, General Government Appropriation Act of 1992 for consolidation of FDA headquarters facilities.
- 4/ Does not include funds requested by GSA for consolidation of FDA headquarters facilities.
- 5/ Does not include appropriated funds requested by GSA for consolidation of FDA headquarters facilities.

**DISTRIBUTION OF RESOURCES
"BUDGET AUTHORITY BY ACTIVITY"**

	FY 1993 Actual		FY 1994 Current Estimate		FY 1995 Estimate	
	\$000	FTE	\$000	FTE	\$000	FTE
Foods						
Chemical Safety of Foods.....	73,273	949	79,344	949	79,344	898
Microbiological Safety of Foods.....	94,295	1,306	102,107	1,306	102,107	1,235
Nutrient Quality and Food Labeling.....	32,518	381	35,212	381	35,212	361
Cosmetic Safety and Labeling.....	4,604	59	4,985	59	4,985	56
	-----	-----	-----	-----	-----	-----
TOTAL, FOODS.....	204,690	2,695	221,648	2,695	221,648	2,550
Human Drugs						
New Drug Evaluation/Orphan Drugs....	75,089	852	90,052	916	99,992	1,049
Orphan Drug Evaluation.....	11,455	16	15,150	16	15,150	15
Generic Drug Evaluation.....	40,025	448	46,724	448	46,724	423
OTC Drug Evaluation.....	7,954	90	7,994	90	7,994	85
Drug Quality Assurance.....	48,591	692	48,840	692	48,840	652
Bioresearch Monitoring.....	12,311	170	16,644	177	18,715	204
Health Fraud.....	4,594	61	4,618	61	4,618	58
Postmarketing Surveillance & Epidemiology.....	7,386	76	7,424	76	7,424	72
Prescription Drug Advertising and Labeling.....	4,242	44	4,264	44	4,264	42
	-----	-----	-----	-----	-----	-----
TOTAL, HUMAN DRUGS.....	211,647	2,449	241,710	2,520	253,721	2,600
Biologics						
Blood & Blood Products.....	51,204	533	52,300	549	55,252	567
Therapeutic Products.....	30,273	279	49,674	312	54,463	374
Vaccines & Allergenic Products.....	16,804	157	29,360	179	32,746	223
	-----	-----	-----	-----	-----	-----
TOTAL, BIOLOGICS.....	98,281	969	131,334	1,040	142,462	1,164

	FY 1993 Actual		FY 1994 Current Estimate		FY 1995 Estimate	
	\$000	FTE	\$000	FTE	\$000	FTE
<u>Animal Drugs and Feeds</u>						
Pre-Approval Evaluation.....	18,319	231	20,061	231	20,061	219
<u>Monitoring of Marketed</u>						
Drugs and Feeds.....	19,698	254	21,572	254	21,572	240
	-----	-----	-----	-----	-----	-----
TOTAL, ADF.....	38,017	485	41,633	485	41,633	459
<u>Devices & Radiological Products</u>						
Surveillance and Enforcement.....	64,165	883	74,975	929	82,291	979
Product Evaluation.....	36,494	459	44,277	509	66,718	795
Education & Assistance.....	15,234	185	19,048	186	19,433	181
Risk Assessment.....	13,132	156	15,014	157	15,372	151
	-----	-----	-----	-----	-----	-----
TOTAL, DEVICES.....	129,025	1,683	153,314	1,781	183,814	2,106
<u>National Center for</u>						
<u>Toxicological Research</u>						
Integrated Research.....	18,251	141	18,677	141	18,677	133
Methods Development.....	14,735	116	15,079	116	15,079	110
	-----	-----	-----	-----	-----	-----
TOTAL, NCTR.....	32,986	257	33,756	257	33,756	243
PROGRAM MANAGEMENT.....	45,442	401	49,012	398	48,973	377
GSA RENT.....	26,066	--	48,575	--	48,575	--
BUILDINGS AND FACILITIES.....	19,664	--	8,350	--	8,350	--
	=====	=====	=====	=====	=====	=====
TOTAL.....	805,818	8,939	929,332	9,176	982,932	9,499
		<u>1/</u>		<u>2/</u>	<u>3/</u>	<u>4/</u>

1/ Reflects comparable transfer of \$2,616,000 and 39 FTE in FY 1993, and \$2,784,000 and 36 FTE in FY 1994 from Office of the Secretary/Office of General Counsel, to FDA's Program Management line. 34 FTE and \$2,745,000 are officially transferred from OS/OGC to FDA in FY 1995.

2/ Includes \$56,284,000 for PDUFA (\$54,000,000 appropriated and a supplemental request of \$2,284,000 to cover inflation). Also includes \$30,000,000 in Devices: \$20,000,000 for Safe Medical Devices Act and \$10,000,000 for Mammography Quality.

3/ Includes \$79,423,000 for PDUFA; \$24,000,000 for Device User Fees; \$6,500,000 for MQSA collections; and deficit user fees of \$228,000,000.

4/ Reflects a reduction of 384 FTE.

FUNDING LEVEL SUMMARY
Department of Health and Human Services
Public Health Service – Food and Drug Administration

Acquired Immune Deficiency Syndrome
(\$000)

<u>Activity</u>	FY 1993 Actual	FY 1994 Appropriation	FY 1995 Estimate
TOTAL FDA	\$72,628	\$72,399	\$72,399
FTEs	667	667	667
 Human Drugs	 25,275	 25,235	 25,235
FTEs	189	189	189
 Biologics	 37,549	 37,408	 37,408
FTEs	371	371	371
 Medical Devices	 9,804	 9,756	 9,756
FTEs	107	107	107

III. Product Research, Evaluation, and Monitoring:

Therapeutic Agents			
\$000	26,002	25,908	25,908
FTEs	198	198	198
Vaccines			
\$000	11,475	11,398	11,398
FTEs	116	116	116
Diagnostic Reagents & Test Kits			
\$000	8,497	8,434	8,434
FTEs	90	90	90
Blood and Blood Products			
\$000	16,922	16,903	16,903
FTEs	156	156	156
Medical Devices			
\$000	9,732	9,756	9,756
FTEs	107	107	107
 TOTAL, FDA			
\$000	\$72,628	\$72,399	\$72,399
FTEs	667	667	667

FOODS

Summary of Project Estimates
(\$000)

	1993 <u>Actual</u>	1994 <u>Appropriation</u>	1994 <u>Current</u> <u>Estimate</u>	Increase or <u>Decrease</u>	1995 <u>Estimate</u>	Increase or <u>Decrease</u>
(\$000)	\$204,690	\$221,648	\$221,648	---	\$221,648	---
FTE	2,695	2,695	2,695	---	2,550	-145

EXPLANATION OF PROGRAM

FDA has the responsibility for ensuring that: foods are safe, sanitary, nutritious, and wholesome; foods are the economic value they purport to be; and cosmetic products are safe. The scope of this responsibility is broad and varied. Foods are subject to natural and man-made contaminants, such as toxins, insects, pathogenic bacteria and viruses, molds, pesticides, industrial chemicals, and toxic metals. In addition, they are subject to numerous additives, some of which have been found to be unsafe for human consumption. FDA carries out its responsibilities through a comprehensive program which includes: applied research aimed at identifying and quantifying potential contaminants or risks present in foods; on-going surveillance of the nation's food supply; and when necessary, imposition of enforcement actions to prevent dangerous commodities and products from reaching the marketplace.

FDA's research activities are directed toward enhancing its ability to properly identify contaminants, their potential risk, and the extent of their presence in foods and/or cosmetics. These applied research activities include:

- Developing new and/or improved analytical methods to detect and quantify microbial pathogens, pesticide and other man-made chemical residues, natural toxins, etc., in foods, as well as to identify and evaluate hazardous substances in cosmetics;
- Improving risk assessment capabilities to more accurately and rapidly assess the degree and severity of potential risks posed by the various foodborne hazards;
- Evaluating the health effects of food contaminants or dietary factors;
- Determining the effects of processing, storage, and preparation on nutrient composition and carcinogen formation;
- Determining the nutrient content and quality of food; and
- Determining consumer practices, knowledge, and attitudes regarding food labeling, handling, preparation, etc.

The Agency applies statutory and regulatory standards in monitoring the food industry to provide the consumer with the best assurances possible that the industry is meeting its responsibility to provide safe, nutritious, and wholesome food to the marketplace. This surveillance aspect of the Food and Cosmetics program includes visits to a wide range of food establishments, collection and analysis of food samples, and implementation of enforcement actions when necessary. These activities include:

- Periodic inspections of domestic food processors and warehouses in the official establishments inventory (OEI) (over 46,000 establishments) to identify and correct safety problems or insanitary conditions;
- Collection and analysis of over 17,000 domestic samples annually to monitor the safety of the domestic food supply;
- Wharf examinations, and sample collections and analyses involving about 9% of the over 1,100,000 lots of food imported annually into the U.S.; and
- Enforcement activities such as warning letters, recalls, seizures, detentions, injunctions, and prosecutions when necessary.

Surveillance efforts are expanded through cooperative relationships with state and local governments, particularly in the areas of food safety at the retail level, safety and quality of shellfish, and the safety of milk products. This is a vast undertaking since the retail food industry alone, includes over 500,000 restaurants or institutional food service outlets, 30,000 supermarkets, 200,000 grocery stores, and 1,500,000 vending sites. Activities in these jointly sponsored regulatory programs include training and technical assistance activities, data sharing, model code development, and sharing of improved analytical methods. The approach to surveillance in the seafood industry will continue to be modified in FY 1995 as the Agency moves toward a Hazard Analysis Critical Control Point (HACCP) system.

In addition to its surveillance activities, the Food and Cosmetics program processed 70 food and color additive petitions in 1993. There are approximately 320 petitions in the current workload and it is estimated that 60 to 70 new petitions will be received each year for consideration of their compliance with FDA regulations.

Program Activity Data

<u>Program Output</u>	<u>1993 Actual</u>	<u>1994 Estimate</u>	<u>1995 Estimate</u>
Food and Color Additive			
Petitions Completed.....	70	70	67
Food Safety Inspections:			
FDA Direct.....	5,900	7,000	6,748
Federal/State Contract.....	7,354	7,350	7,350
Food Economics Inspections....	566	400	378
Cosmetics Inspections.....	227	200	189
Wharf Examinations & Import			
Sample Collections.....	77,204	69,700	65,950
Food Safety Samples Analyzed			
Domestic.....	17,201	21,200	20,059
Import.....	22,601	28,260	26,740
Food Economics Samples			
Analyzed.....	4,333	4,000	3,785
Cosmetic Samples Analyzed.....	426	300	284

RATIONALE FOR BUDGET REQUESTDecrease:

The FY 1995 request of \$221,648,000 continues funding at the FY 1994 level. To continue efforts to support streamlining the Federal Government, FDA will be absorbing all inflationary increases in FY 1995. As a result of these efforts the Foods program will be adjusting their FTE level downward by 145 FTEs, as FDA meets the FTE levels needed in areas of high priority such as the Safe Medical Devices Act, the Mammography Quality Standards Act, the Prescription Drug User Fee Act and Medical Device User Fees.

Distribution of FTEs by Project Activity

<u>Food and Cosmetics:</u>	<u>1993 Actual</u>	<u>1994 Estimate</u>	<u>1995 Estimate</u>
Chemical Safety of Foods.....	949	949	898
Microbiological Safety of Foods..	1,306	1,306	1,235
Nutrient Quality and			
Food Labeling.....	381	381	361
Cosmetic Safety and Labeling.....	59	59	56
TOTAL.....	2,695	2,695	2,550

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Human Drugs

Summary of Project Estimates
(\$000)

	1993 <u>Actual</u>	1994 <u>Appropriation</u>	1994 <u>Current</u> <u>Estimate</u>	Increase or <u>Decrease</u>	1995 <u>Estimate</u>	Increase or <u>Decrease</u>
(\$000)	\$211,647	\$240,527	\$241,710	+\$1,183	\$253,721	+\$12,011
FTE	2,449	2,520	2,520	---	2,600	80
AIDS						
(non-add)						
(\$000)	(\$25,275)	(\$25,235)	(\$25,235)	---	(\$25,235)	---
FTEs	(189)	(189)	(189)	---	(189)	---

EXPLANATION OF PROGRAM

The Food and Drug Administration (FDA) has responsibility for the regulation of drug products intended for use in the prevention, diagnosis, and treatment of diseases in humans. These products are essential elements of the health care delivery system of this country. Accordingly, the availability of a reliable supply of safe and effective drug products is of great importance to the public health. To carry out this responsibility, the Human Drugs program ensures that regulated products are safe, effective, and properly labeled for their intended uses, and that clinical research on investigational drugs adequately protects the rights of human subjects. Major objectives in support of this mission are to (1) review and approve only those drug products that are evaluated as safe and effective under the regulations; (2) monitor the safety of drugs through programs such as the adverse drug reaction reporting system and the drug product problem reporting system; (3) conduct establishment inspections, sample collection and analyses; (4) develop and maintain the scientific research and improved management information systems capability necessary to achieve greater efficiency and effectiveness of operations; and, (5) promote informational and educational programs addressing both medical and consumer interests.

As the regulatory agency responsible for the safety of the nation's drugs and biologics, FDA is responsible also for ensuring that the drugs applicable the treatment of to narcotic addiction are safe and effective, and that the practices of methadone programs comply with Federal regulations which establish standards for registration and treatment of narcotic addiction.

New drug approvals soared during 1993 -- FDA approved 370 new drug, generic drug and biological product applications during the Calendar year. Twenty-five of the new drug approvals are for new molecular entities (NMEs), drugs which are distinctly different in

structure from those already on the market. Thirteen of the "twenty-five" new prescription drugs are in the "priority" classification -- drugs expected to have important therapeutic value. Also, nine orphan drugs were approved, of which six are NMEs.

Some of the priority therapies approved in 1993 were: Cognex, the first product ever approved to treat Alzheimer's disease; Flumadine for the flu; Mepron for the treatment of AIDS patients; Felbatol for the treatment of epileptic seizures. The experimental AIDS drug, Stavudine, was made available for expanded investigational use under the Agency's "parallel track" policy, in which promising new drugs for treating AIDS and other life-threatening diseases are made available to persons either unable to take standard therapy or unable to participate in controlled studies. The Agency also allowed a treatment IND for an experimental drug, Copolymer, a promising treatment for multiple sclerosis (MS) patients.

A new postmarket surveillance program called MEDWatch was implemented in 1993. The MEDWatch program seeks to persuade more health care professionals to report adverse drug events and problems, and to improve the quality of the reports. FDA has developed new forms to facilitate adverse event reporting and has also established a special round-the-clock toll-free telephone line for adverse event reporting and information.

Responsibility for ensuring the safety and effectiveness of over-the-counter (OTC) drugs entails the establishment, through rule-making procedures, of standards for OTC drugs through the publication of monographs, or regulations, in the Federal Register. During FY 1993, the Agency published 28 monographs and monograph amendments. There are presently 44 monographs under development which includes monographs and amendments to previously published monographs.

Program Activity Data

Program Output

	<u>1993 Actual</u>	<u>1994 Estimate</u>	<u>1995 Estimate</u>
Total New Drug Application (NDA) Reviews.....	240	275	300
NDAs approved.....	83	90	100
Time from Receipt to Approval (mos.) (mean).....	(34.3)	(26.9)	(21.5)
Time from Receipt to Approval (mos.) (median).....	(26.8)	(21.4)	(17.2)
NDA Supplemental Reviews.....	2,028	2,100	2,200
Abbreviated New Drug Application (ANDA) Actions 1/.....	1,177	1,295	1,425
ANDA Approvals.....	215	240	260
Average Review Time from ANDA Receipt to Approval (mos.) 2/	38.0	32	28
ANDA Supplemental Actions 3/.....	3,969	4,160	4,370
INDs (Active).....	10,682	10,800	10,900
Bioequivalence Reviews.....	717	767	821
Inspections.....	4,474	4,550	4,600
Drug Sample Analyses.....	4,296	5,600	5,600
Non-clinical/clinical Study Investigations.....	440	470	500
OTC Monographs Under Development..	44	38	31
Adverse Reaction Report Reviews.	149,000	170,000	180,000

- 1/ Total of approvals, not approvable, tentative approvals, and approvable.
- 2/ Reflects pharmaceutical manufacturers' management decision to focus on the resolution of particularly old applications. Estimate includes time in FDA to conduct reviews as well as time with firm to resolve deficiencies.
- 3/ Total of approvals, not approvable, conditional approvals, and approvable.

RATIONALE FOR BUDGET REQUEST

Increases:

Prescription Drug User Fee Act - \$12,011,000

To continue carrying out the Prescription Drug User Fee Act, (PDUFA) the FY 1995 budget includes an additional increment of \$12,011,000, and 160 FTE for a total of \$41,194,000 and 250 FTE, in the Human Drugs program. The total amount included in our FY 1995 request for the Human Drugs and Biologics programs is \$79,423,000. Revenues generated from user fees paid by the pharmaceutical and biological prescription drug industries would be dedicated for the use in expediting the prescription drug review and approval process.

The \$79,423,000 in user fees, and the utilization of an additional 319 FTE for a total of 500 FTE, in FY 1995 will enable FDA to meet its FY 1995 goals as contained in the Act.

1. By the end of the first quarter of FY 1995:
 - Fifty-five percent of the requested FDA review staff will have been recruited and brought on-board.
 - The project management methodology for all PLA/ELA reviews will be implemented.
 - The overdue backlogs of efficacy and manufacturing supplements to NDAs will be eliminated.
2. By the end of the third quarter of FY 1995:
 - Review and act on all NDAs on Human Drugs' October 1, 1992, overdue list.
 - Review and act on the backlog of all PLAs, ELAs, and PLA amendments on CBERs list of October 1, 1992.
3. Uniform CANDAs standards will be adopted during FY 1995.
4. Each of the fifty-five percent application goals of FY 1994 is increased to 70%.

Decrease:

The FY 1995 request of \$253,721,000 continues funding at the FY 1994 level. To continue efforts to support streamlining the Federal Government, FDA will be absorbing all inflationary increases in FY 1995. As a result of these efforts the Human Drugs program will be adjusting their FTE level downward by 80 FTEs in nonprescription drug user fee activities, as FDA meets the FTE levels needed in areas of high priority such as the Safe Medical Devices Act, the Mammography Quality Standards Act, the Prescription Drug User Fee Act and Medical Device User Fees.

Distribution of FTEs by Project Activity

	1993	1994	1995
<u>Human Drugs</u>	<u>Actual</u>	<u>Estimate</u>	<u>Estimate</u>
Bioresearch Monitoring.....	170	177	204
Drug Quality Assurance.....	692	692	652
Generic Drug Evaluation.....	448	448	423
Health Fraud.....	61	61	58
New Drug Evaluation/Orphan Drugs.	852	916	1,049
Over-the-Counter Drug Evaluation.	90	90	85
Post-marketing Surveillance and			
Epidemiology.....	76	76	72
Prescription Drug Advertising....	44	44	42
Total.....	2,449	2,520	2,600
AIDS FTEs Included Above.....	(189)	(189)	(189)

Orphan Product Development Activities

	1993 <u>Actual</u>	1994 <u>Estimate</u>	1995 <u>Estimate</u>
Intramural Activities: (\$000)			
Orphan Drugs Project.....	\$ 1,433	\$ 1,950	\$1,950
Related Activities in Foods, Devices and Radiological Products, and NCTR Programs.....	<u>877</u>	<u>1,200</u>	<u>1,200</u>
Total, Intramural Oblig...	\$2,310	\$3,150	\$3,150
Grants and Contracts.....	<u>9,145</u>	<u>12,000</u>	<u>12,000</u>
Total Obligations.....	\$11,455	\$15,150	\$15,150
Number of Grants Awarded:			
New.....	18	34	34
Continuing.....	<u>45</u>	<u>28</u>	<u>28</u>
Total number of grants.	63	62	62

EXPLANATION OF PROGRAM

FDA continues to carry out a program encouraging the development of drugs, biologicals, medical devices and medical foods for rare diseases and conditions. The Orphan Products Grants Program is an increasingly important focus of the Office of Orphan Products Development (OPD). Congress has appropriated \$15.150 million for FY 1994.

Children are often a special class of orphans - products that are approved for use in adults are often not tested in and labeled for children. Because these products are already available, sponsors may not want to go to the trouble and expense of doing pediatric studies and developing pediatric dosages. Several studies funded by the OPD grants program are looking at already approved products for use in children. Examples are pentamidine for prevention and treatment of pneumocystis carinii pneumonia in pediatric AIDS patients and naltrexone, a narcotic antagonist, to treat autism in children.

RATIONALE FOR BUDGET REQUEST

The FY 1995 request of \$15,150,000 continues funding at the FY 1994 level. To continue efforts to support streamlining the Federal Government, FDA will be absorbing all inflationary increases in FY 1995.

Drug Control Program

Summary of Project Estimates
(\$000)

	1993	1994	1994	Increase		Increase
	<u>Actual</u>	<u>Appropriation</u>	<u>Current</u>	<u>or</u>	1995	<u>or</u>
			<u>Estimate</u>	<u>Decrease</u>	<u>Estimate</u>	<u>Decrease</u>
Regulation of Methadone (\$000)	\$6,575	\$6,800	\$6,800	---	\$6,800	---

EXPLANATION OF PROGRAM

FDA places a high priority on the review of new drug applications for drugs which alleviate narcotic dependency. In particular, the Agency works closely with NIH, especially NIDA to expedite the development of such drugs that are under study by NIH institutes. The treatment of drug addicts with dependency-reducing drugs may not only lead to a reduction in illicit drug usage but may also lead to a reduction in the spread of AIDS which is prevalent among I.V. drug abusers.

Applications from hospitals and narcotic treatment programs for use of methadone in the treatment of narcotic addiction are reviewed and only those that comply with the narcotic treatment standards published jointly by FDA and the National Institute for Drug Abuse are approved. Over 1,000 methadone treatment programs have been approved in the U.S. In addition to the review of applications for new programs, existing treatment programs are monitored for compliance with regulatory standards. Our goal in this regard is to inspect each program every two years. We evaluate inspection results to determine the appropriate follow-up to achieve compliance with the regulatory standards. In addition, we evaluate proposals (exemptions from regulations) submitted by individual treatment programs for modifying treatment standards. The agency plans to continue these methadone treatment program oversight activities at this level in FY 1995.

With the passage of new legislation in 1990, which reassigned the responsibility of investigating the illegal use of anabolic steroids to DEA as a controlled substance, our role in this area was reduced. We continue to investigate new chemical substances which are being abused and a Memorandum of Understanding has been developed between DEA and FDA which describes the mutual roles of each agency in this regard.

Objectives:

In keeping with its responsibilities, FDA has the following objectives:

- 1) ensure the expeditious review of applications for new drugs intended to alleviate narcotic addiction;
- 2) ensure that practices of narcotic treatment programs comply with Federal regulations which establish the standards for registration and treatment of narcotic addiction.

RATIONALE FOR BUDGET REQUEST

The FY 1995 request of \$15,150,000 continues funding at the FY 1994 level. To continue efforts to support streamlining the Federal Government, FDA will be absorbing all inflationary increases in FY 1995.

Relationship to Other Federal Programs:

Our drug abuse program is maintained in close harmony with the programs of SAMHSA, DEA, and other Federal agencies. FDA chairs the Interagency Methadone Policy Review Board (with NIDA, VA, DEA, ONDCP, and SAMHSA) which meets on a bimonthly basis to evaluate overlapping issues and concerns to the agencies with oversight responsibilities. We are continuing our traditional role of consulting with the DEA on issues such as the proper medical uses, and the level of drugs needed for such uses, of controlled substances.

Workload:

PROGRAM OUTPUTS - FDA DRUG CONTROL PROGRAM
FY 1993 - FY 1995

	FY 1993 <u>Actual</u>	FY 1994 <u>Estimate</u>	FY 1995 <u>Estimate</u>
Inspection Program:			
Narcotic treatment centers	356	356	356

BIOLOGICS

Summary of Project Estimates
(\$000)

	1993 <u>Actual</u>	1994 <u>Appropriation</u>	1994 <u>Current</u> <u>Estimate</u>	Increase or <u>Decrease</u>	1995 <u>Estimate</u>	Increase or <u>Decrease</u>
(\$000)	\$98,281	\$130,233	\$131,334	+\$1,101	\$142,462	+\$11,128
FTE	969	1,040	1,040	---	1,164	159

AIDS

(non-add)

(\$000)	(\$37,549)	(\$37,408)	(\$37,408)	---	(\$37,408)	---
FTEs	(371)	(371)	(371)	---	(371)	---

EXPLANATION OF PROGRAM

The availability of safe and effective biological products for disease prevention and treatment and the assurance of the safety of the nation's blood supply is an essential element of the nation's health care delivery system. FDA is responsible for assuring that blood and blood products, blood test kits, bacterial vaccines and antigens, viral vaccines, therapeutic agents, and other biological products intended for use in the prevention, diagnosis, and treatment of disease in humans are pure, potent, safe, and effective, as well as properly labeled for their intended uses.

FDA's biologics program includes registration and inspection of blood banks and other firms processing blood; licensing and inspection of firms collecting human source plasma; evaluating and licensing biologics manufacturing firms and products; lot release of licensed products; removal of ineffective, unsafe, or improperly labeled products from the market; development of necessary regulations, compliance programs and guidelines; and the conduct of research, in concert with other PHS agencies, academia, and industry, to further the development of new products and to provide a sound scientific basis for their regulation. The agency sponsors and conducts AIDS-related research to foster the development of new biological products and regulated marketed biologics intended for use in the prevention, treatment, and diagnosis of AIDS and AIDS-related diseases. In addition, the Agency seeks to improve the safety of childhood vaccines by sponsoring and conducting research toward the development of vaccines that are less reactogenic. FDA ensures that childhood vaccines are safe and effective through evaluation of products, their manufacture, and by monitoring adverse events associated with immunization.

Program Activity Data

<u>Program Output</u>	<u>1993 Actual</u>	<u>1994 Estimate</u>	<u>1995 Estimate</u>
License Application Reviews....	2,460	2,829	3,140
IND Amendments.....	8,100	8,300	9,213
Non-clinical/Clinical Study Investigations.....	72	120	133
Inspections.....	3,057	3,240	3,596

RATIONALE FOR BUDGET REQUEST

Increases:**Prescription Drug User Fee Act - \$11,128,000**

To continue carrying out the Prescription Drug User Fee Act, (PDUFA) the FY 1995 budget includes an additional increment of \$11,128,000 and 159 FTE, for a total of \$38,229,000 and 250 FTE, in the Biologics program. The total amount included in our FY 1995 request for the Biologics and Human Drugs programs is \$79,423,000. The revenues generated from fees paid by the pharmaceutical and biological prescription drug industries would be dedicated for the use in expediting the prescription drug review and approval process.

The \$79,423,000 in user fees, and the utilization of an additional 319 FTE for a total of 500 FTE, in FY 1995 will enable FDA to meet its FY 1995 goals as contained in the Act, assuming positive action on the FY 1995 request.

1. By the end of the first quarter of FY 1995:

- Fifty-five percent of the requested FDA review staff will have been recruited and brought on-board.
- The project management methodology for all PLA/ELA reviews will be implemented.
- The overdue backlogs of efficacy and manufacturing supplements to NDAs will be eliminated.

2. By the end of the third quarter of FY 1995:

- Review and act on all NDAs on Human Drugs' October 1, 1992, overdue list.
- Review and act on the backlog of all PLAs, ELAs, and PLA amendments on CBERS list of October 1, 1992.

3. Uniform CAPLA standards will be adopted during FY 1995.

4. Each of the fifty-five percent application goals of FY 1994 is increased to 70%.

Decrease:

The FY 1995 request of \$142,462,000 continues funding at the FY 1994 level. To continue efforts to support streamlining the Federal Government, FDA will be absorbing all inflationary increases in FY 1995. As a result of these efforts the Biologics program will be adjusting their FTE level downward by 35 FTEs in nonprescription drug user fee activities, as FDA meets the FTE levels needed in areas of high priority such as the Safe Medical Devices Act, the Mammography Quality Standards Act, the Prescription Drug User Fee Act and Medical Device User Fees.

Distribution of FTEs by Project Activity

<u>Biologics</u>	1993 <u>Actual</u>	1994 <u>Estimate</u>	1995 <u>Estimate</u>
Vaccines & Allergenic Products.....	157	179	223
Blood and Blood Products....	533	549	567
Therapeutic Products.....	<u>279</u>	<u>312</u>	<u>374</u>
Total.....	969	1,040	1,164
AIDS FTEs Included Above....	(371)	(371)	(371)

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Animal Drugs and Feeds

Summary of Project Estimates (\$000)

	1993 <u>Actual</u>	1994 <u>Appropriation</u>	1994 <u>Current</u> <u>Estimate</u>	Increase or <u>Decrease</u>	1995 <u>Estimate</u>	Increase or <u>Decrease</u>
(\$000)	\$38,017	\$41,633	\$41,633	---	\$41,633	---
FTE	485	485	485	---	459	-26

EXPLANATION OF PROGRAM

The goal of the Animal Drugs and Feeds program is to assure that only safe and effective animal drugs, devices, feeds and food additives are marketed; and that foods from animals that are administered drugs and food additives, in accordance with label directions, are safe for human consumption.

Veterinary drugs are used to treat or prevent diseases in animals and to improve production of food-producing animals. FDA is responsible for reviewing New Animal Drug Applications (NADAs) and Abbreviated New Animal Drug Applications (ANADAs) to ensure that the drugs are safe and effective for animals and that foods from these animals are safe before the drugs are approved for marketing. The Agency maintains continuing surveillance over all animal drugs, devices, and feeds marketed in interstate commerce to ensure their compliance with the Food, Drug and Cosmetic (FD&C) Act.

Data integrity continues to be a very high priority for this program. A major objective in this regard is to strengthen FDA monitoring of the significant research associated with the approval of new animal drugs. It is important to ensure the validity of these pivotal studies through audits of the system industry uses in collecting, storing, and summarizing the scientific data it uses. The strategy for addressing the issues concerning the integrity of the product review process of the Animal Drugs and Feeds program in 1995 includes inspections of clinical investigations, data audits, and preapproval inspections of manufacturing establishments.

Surveillance of marketed products and agribusiness industry is accomplished through review of drug experience reports and compliance programs implemented by the FDA field offices through inspections, sample collections and analysis, investigations, and other activities. Regulatory actions are taken as needed to control violative goods and firms.

One major use of animal drugs is in animal feeds. Because of the large number of facilities subject to inspection, and for more efficient utilization of FDA's limited resources, FDA approaches

the medicated feed area through a federal/state partnership. The Agency's medicated feed program was remodeled to focus attention principally on those drugs added to animal feeds which have the most potential for causing unsafe tissue residues. This remodeling has helped FDA to utilize its limited resources in a much more effective manner.

Research is another critical element in assuring the safety and efficacy of animal drugs and feed additives. Included are pharmacokinetics, toxicology, and tissue residue studies on food producing animals as well as research to develop analytical methods, e.g., evaluation of screening tests to detect drug residues in milk. FDA directs significant efforts toward research programs to provide better science for the regulation of animal drugs with human health impact. In addition, the Agency will continue to emphasize its minor use drug research program to promote the availability of drugs for minor species and for minor uses in the major species.

Program Output Data

	1993 <u>Actual</u>	1994 <u>Estimate</u>	1995 <u>Estimate</u>
Establishment Inspections.....	815	700	662
Feed Mill FDA-Inspections.....	263	400	379
Feed Mill Inspections conducted by States under FDA contract.	558	550	550
Sample Analysis.....	1,889	2,300	2,177
Manufacturers' Drug Experience Reports Reviewed.....	3,029	3,400	3,218
Adverse Reaction Reports Reviewed.....	1,501	1,600	1,514
Medicated Feed Applications Processed.....	2,293	4,000	3,786
Investigational Animal Food Additive Applications.....	38	60	57
Animal Food Additive Petitions.	10	20	19
New Animal Drug Applications (NADA)			
Received.....	733	750	750
Processed.....	609	750	710
Abbreviated New Animal Drug Applications (ANADA)			
Received.....	99	110	110
Processed.....	76	110	104
Investigational New Animal Drug Files			
Received.....	4,147	4,500	4,500
Processed.....	3,881	4,000	3,786
Abbreviated Investigational New Animal Drug Files			
Received.....	179	200	200
Processed.....	177	200	189
Original NADAs Approved.....	8	20	19
Aver. Time From Receipt to Approval (Orig. NADAs) (mos.)	(52)	(50)	(48)
Original ANADAs Approved.....	7	7	7
Aver. Time From Receipt to Approval (Orig. ANADAs) (mos.)	(20)	(18)	(16)

RATIONALE FOR BUDGET REQUEST

Decrease:

The FY 1995 request of \$41,633,000 continues funding at the FY 1994 level. To continue efforts to support streamlining the Federal Government, FDA will be absorbing all inflationary increases in FY 1995. As a result of these efforts the Animal Drugs and Feeds program will be adjusting their FTE level downward by 26 FTEs, as FDA meets the FTE levels needed in areas of high priority such as the Safe Medical Devices Act, the Mammography Quality Standards Act, the Prescription Drug User Fee Act and Medical Device User Fees.

Distribution of FTEs by Project Activity

	1993 <u>Actual</u>	1994 <u>Estimate</u>	1995 <u>Estimate</u>
Pre-Approval Evaluation.....	231	231	219
Monitoring of Marketed Drugs and Feeds.....	<u>254</u>	<u>254</u>	<u>240</u>
TOTAL, ADF.....	485	485	459

Devices and Radiological Products

Summary of Project Estimates (\$000)

	1993	1994	1994	Increase	1995	Increase
	<u>Actual</u>	<u>Appropriation</u>	<u>Current</u>	<u>or</u>	<u>Estimate</u>	<u>or</u>
			<u>Estimate</u>	<u>Decrease</u>		<u>Decrease</u>
(\$000)	\$129,025	\$153,314	\$153,314	---	\$183,814	+\$30,500
FTE	1,683	1,781	1,781	---	2,106	325
AIDS						
(non-add)						
(\$000)	(\$9,804)	(\$9,756)	(\$9,756)	---	(\$9,756)	---
FTE	(107)	(107)	(107)	---	(107)	---

EXPLANATION OF PROGRAM

The Food and Drug Administration pursues two primary goals under the Medical Devices and Radiological Products program: 1) to ensure the safety and effectiveness of medical devices; and 2) to eliminate unnecessary exposure to radiation from medical, industrial, and consumer products while maximizing the benefits from necessary exposure.

Medical devices are regulated pursuant to the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990. Radiation-emitting electronic products are regulated pursuant to the Radiation Control for Health and Safety Act of 1968 and the Mammography Quality Standards Act of 1992.

FDA employs a wide variety of regulatory mechanisms to ensure the safety and effectiveness of medical devices. All devices are classified into three categories, depending on the level of regulation required to ensure safety and effectiveness. Class I devices are subject to general controls, such as Good Manufacturing Practices requirements, labeling requirements, and registration with FDA. Class II devices are subject to special controls, such as performance standards, special postmarket surveillance efforts, and patient registries. Class III devices are required to undergo pre-market evaluation and receive FDA approval prior to being marketed. Through the authorities delegated to FDA to implement MQSA, FDA will ensure that women have access to safe and effective mammography services.

Postmarket surveillance activities, such as the MedWatch mandatory and voluntary Medical Device Reporting program, and inspections of manufacturing plants help ensure the continued safety and effectiveness of marketed devices. These activities also provide an early warning of problems, allowing FDA and industry to take corrective action before the public health is threatened.

**MEDICAL DEVICES AND RADIOLOGICAL HEALTH
Workload Data**

<u>Program Workload and Outputs</u>	<u>FY 1993 Actual</u>	<u>FY 1994 Estimate</u>	<u>FY 1995 Estimate</u>
Premarket Approval Applications (PMAs):			
Received	40	60	62
Decisions	68	80	93
Approved	24	28	33
Average PMA review time (FDA days)*.....	328	375	340
PMA Supplements:			
Received	395	600	624
Decisions	569	740	830
Average PMA Supp. review time (FDA days)*	168	200	180
Premarket Notifications - 510(k)s:			
Received	6,288	6,540	6,800
Decisions	5,073	6,000	7,000
Average 510(k) review time (FDA days)*..	162	175	165
Investigational Device Exemptions (IDEs):			
Received	241	250	260
Decisions	248	250	260
Average IDE review time (FDA days).....	30	30	30
IDE Supplements:			
Received	3,668	3,800	3,950
Decisions	3,814	3,800	3,950
Medical Device Reports: **+			
Received.....	87,728	156,000	246,000
Reviewed	45,162	163,100	264,000
User Facility Reports:**			
Received	2,325	5,100	10,200
Reviewed	3,400	5,100	10,200
Distributor Reports:**			
Received	1,121	1,400	2,800
Reviewed	1,121	1,400	2,800
MDR Monthly Reports from Manufacturers:**			
Received	N/A	3,600	7,900
Reviewed	N/A	3,600	7,900
MedWatch Voluntary Reporting Program:			
Received	3,690	6,000	9,000
Reviewed	1,845	3,400	5,400
Inspections -(100% FDA).....	3,451	3,500	3,600
MQSA..(includes 75% State/25% Federal)	N/A	N/A	10,000

* As a result of the increased number of decisions, the average time to review applications will rise even with increased resources because it will take time for the rate of outputs to equal the rate of receipts. When outputs exceed inputs, the applications under review the longest will be completed first.

** The MedWatch mandatory program.

+ User Facility and distributor reports are included in the total medical device reports.

NOTE: The new MDR regulation, expected to be published in FY 94, requires monthly reports from manufacturers and semi-annual reports from user facilities. This new requirement will allow FDA to conduct an indirect review on many of the individual reports submitted with the monthly summaries from the manufacturers. Analysis will be conducted on all the monthly summaries and the individual reports that indicate a problem requiring further investigation. The MedWatch data in this report reflect the number of reports and not the actual number of incidents.

RATIONALE FOR BUDGET REQUEST

Increases:**MEDICAL DEVICES - \$24,000,000 and 246 FTEs**

The Food and Drug Administration requests increased funding for the Medical Device Program in the amount of \$24,000,000 to enhance its ability to ensure the safety and effectiveness of medical devices. The Medical Device Program will use these funds and 246 FTEs to virtually eliminate product review backlogs within two years; accelerate time frames for product reviews; implement process improvements/guidance to industry; improve scientific capabilities to support risk assessment decisions; and upgrade the program's Management Information System capabilities to integrate information needed for product review and postmarket management. FDA proposes that these funds be derived from user fees specifically authorized by Congress.

FDA has met with industry representatives over the last few months and significant agreement has been reached on the need for program improvements financed by industry fees; the principles underlying collection and use of user fees; performance goals for FDA; FDA management initiatives to be undertaken; and a preferred fee structure concept. FDA and industry believe that the following guiding principles are key to successfully establishing these additional user fees. They must be:

- viewed as providing a complementary set of incentives to industry;
- based on new legislative authority featuring administrative simplicity and efficiency, providing for implementation without exhaustive rulemaking; and
- structured to stable sources of revenue with adequate growth potential.

The Agency's FY 1995 request will be used to virtually eliminate the large application backlog by the end of FY 1996--a two-year time frame beginning at the start of FY 1995. After the backlog has been reduced to manageable levels, then the Agency will be able to use the resources to maintain the statutory time frames and/or the agreed-upon performance goals. The additional resources coming from user fees, coupled with specific management initiatives which are currently being implemented, will assure that the predictability of review times sought by industry will be achievable by the start of FY 1997.

Mammography Quality Standards Act of 1992

In FY 1995, FDA proposes to use an additional 31 FTEs for a total of 61 FTEs to continue implementation of the Mammography Quality Standards Act of 1992 (MQSA). Breast cancer is the second leading cause of cancer deaths among women. Mammography or x-ray examination of the breast, when conducted properly, is an effective tool in reducing mortality. Implementation of this Act will provide quality preventive health care for women by eliminating substandard mammography facilities and requiring the remaining facilities to achieve and maintain a high standard of safety and accuracy.

The FY 1995 activities will include: funding of a National Advisory Committee; continued development of the regulatory programs for accreditation entities and mammography facilities; certification and inspection of accreditation entities; facility inspections to evaluate accreditation entity/State performance; purchase of equipment, development of instrument calibration procedures, and initial calibration of instruments; annual inspections of more than 10,000 mammography facilities; design, programming and maintenance of data systems required to monitor inspection activities; user education and assistance, and compliance and enforcement activities.

The Mammography Quality Standards Act of 1992 requires that any facility producing, processing, or interpreting mammographic images must be certified by the Secretary of HHS by October 1, 1994, to remain in operation. In order for FDA to meet the statutory timeframe, Congress enacted a technical amendment in December 1993 that authorized FDA to issue immediately enforceable interim regulations. MQSA requires annual inspections of certified facilities to determine compliance with quality standards and authorizes user fees to cover the costs of these inspections. The budget includes specific appropriations language to permit FDA to finance inspections conducted in 1995 from general revenues. In addition, FDA expects to begin conducting inspections and collecting fees in FY 1995. FDA expects to collect \$6,500,000 in user fees in FY 1995 for these inspections to capitalize funding for future year inspection activities.

Decreases:

The FY 1995 request of \$183,314,000 continues funding at the FY 1994 level. To continue efforts to support streamlining the Federal Government, FDA will be absorbing all inflationary increases in FY 1995. As a result of these efforts, the Medical Devices program will be adjusting their FTE level downward by 65 FTEs in non-review activities, as FDA meets the FTE levels needed in areas of high priority such as the Safe Medical Devices Act, the Mammography Quality Standards Act, the Prescription Drug User Fee Act and Medical Device User Fees.

Distribution of FTEs by Project Activity

<u>Devices & Radiological Products</u>	<u>1993 Actual</u>	<u>1994 Estimate</u>	<u>1995 Estimate</u>
Surveillance & Enforcement.....	883	929	979
Product Evaluation.....	459	509	795
Risk Assessment.....	156	157	151
Education and Assistance.....	<u>185</u>	<u>186</u>	<u>181</u>
Total.....	1,683	1,781	2,106
AIDS FTEs Included Above.....	(107)	(107)	(107)

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NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

Summary of Project Estimates

(\$000)

	1993 <u>Actual</u>	1994 <u>Appropriation</u>	1994 Current <u>Estimate</u>	Increase or <u>Decrease</u>	1995 <u>Estimate</u>	Increase or <u>Decrease</u>
(\$000)	\$32,986	\$33,756	\$33,756	---	\$33,756	---
FTE	257	257	257	---	243	-14

EXPLANATION OF PROGRAM

NCTR programs focus on the major research goals of the Agency. Two overall goals that address the Agency's needs are: (1) to integrate research in order to provide more effective risk measures for FDA regulated products; and (2) to support FDA enforcement through development of analytical methods. Continued efforts are underway to establish strong Agency-wide research initiatives specifically directed towards addressing important regulatory concerns.

Through integrated research, NCTR continues to focus on improving the standard bioassay through six mechanistic studies: biochemical and molecular markers of cancer, secondary mechanisms of toxicity, solid-state toxicity, nutritional modulators of risk and toxicity, quantitative risk assessment, and transgenics. The bioassay will form the basis for using animal data to assess human risks.

NCTR's analytical methods development activities include projects in conjunction with other centers to develop sensitive techniques to measure adulterants to the food supply, such as lead in food supplements and microbial contaminants in disinfectants used to sterilize medical devices. Other studies are underway to develop methods to measure compounds that may adversely affect human development, such as phytoestrogens (plant chemicals with estrogenic properties) and techniques to measure the neurotoxic effects of anti-HIV chemicals.

RATIONALE FOR BUDGET REQUEST

Decreases:

The FY 1995 request of \$33,756,000 continues funding at the FY 1994 level. To continue efforts to support streamlining the Federal Government, FDA will be absorbing all inflationary increases in FY 1995. As a result of these efforts NCTR will be adjusting their FTE level downward by 14 FTEs, as FDA meets the FTE levels needed in areas of high priority such as the Safe Medical Devices Act, the Mammography Quality Standards Act, the Prescription Drug User Fee Act and Medical Device User Fees.

Distribution of FTEs by Project Activity

National Center for <u>Toxicological Research</u>	1993 <u>Actual</u>	1994 <u>Estimate</u>	1995 <u>Estimate</u>
Integrated Research.....	141	141	133
Methods Development.....	<u>116</u>	<u>116</u>	<u>110</u>
Total.....	257	257	243

PROGRAM MANAGEMENT

Summary of Project Estimates
(\$000)

	1993 <u>Actual</u>	1994 <u>Appropriation</u>	1994 Current <u>Estimate</u>	Increase or <u>Decrease</u>	1995 <u>Estimate</u>	Increase or <u>Decrease</u>
\$(000)	\$45,442	\$46,228	\$49,012	+\$2,784	\$48,973	-\$39
FTE	401	362	398	+36	377	-21

EXPLANATION OF PROGRAM

This activity provides central program direction and administrative services for Agency programs to ensure that FDA's consumer protection efforts are effectively managed and that available resources are put to the most efficient use. Functions include providing agency-wide policy development in medical affairs, scientific coordination, regulatory requirements, legislation, planning and evaluation, consumer communications, and public information; and management expertise and coordination in financial management, personnel, contracts and grants administration, procurement/property/space control, and communications systems.

Specific programs within this activity are management of Freedom of Information (FOI) activities, to respond within statutory timeframes to inquiries; administration of internal controls required under the Federal Managers Financial Integrity Act; and, the Small Business Program, to assist small businesses in carrying out regulatory requirements and in participating in FDA's regulatory decision-making process.

RATIONALE FOR BUDGET REQUEST

Increase:

FDA's FY 1995 Program Management budget includes 34 FTE and \$2,745,000 to be transferred from the Office of the Secretary/Office of General Counsel budget. This transfer will accommodate the increasing demand for certain legal services which is being generated by expansion of Agency program goals and objectives. It will also allow FDA and the Department to evaluate the efficacy of decentralizing the provision of legal services through the establishment of an organizational legal component within FDA.

Decrease:

The FY 1995 request of \$48,973,000 continues funding at the FY 1994 level. To continue efforts to support streamlining the Federal Government, FDA will be absorbing all inflationary increases in FY 1995. As a result of these efforts Program Management will be adjusting their FTE level downward by 21 FTEs, (which includes the net reduction of comparable OGC FTE) as FDA meets the FTE levels needed in areas of high priority such as the Safe Medical Devices Act, the Mammography Quality Standards Act, the Prescription Drug User Fee Act and Medical Device User Fees.

RENTAL PAYMENTS TO GSA

Appropriation Summary
(\$000)

	1993	1994	1994	Increase	1995	Increase
	<u>Actual</u>	<u>Appropriation</u>	<u>Current</u>	<u>or</u>	<u>Estimate</u>	<u>or</u>
			<u>Estimate</u>	<u>Decrease</u>	<u>Estimate</u>	<u>Decrease</u>
(\$000)	\$26,066	\$48,575	\$48,575	---	\$48,575	---

EXPLANATION OF PROGRAM

From Fiscal Years 1988 through 1993 Congress capped FDA's rental payments to GSA at \$25,612,000, although the actual rates projected by GSA were consistently higher. The FY 1994 President's Budget proposed an increase in this payment to \$48,575,000, which was appropriated. However, Congress directed that \$15,000,000 be reserved from this account for use by FDA to "assist GSA and lessen its burden... to reduce the backlog of existing GSA responsibilities".

FDA uses about 2.8 million net square feet of space covered by GSA rental charges. About 50 percent of these charges are for facilities in the Washington area, of which the largest are the Parklawn Building and Federal Building 8. The major field expenses, of course, are for the Agency's District Offices, although the Agency also has about 130 small leased offices as resident posts for field investigators, which provide significant savings in time as well as travel costs, and provide for a wide geographic dispersion of FDA staff to enable them to respond to emergency situations.

Rental costs do not apply to those facilities owned and operated by FDA, including primarily the National Center for Toxicological Research and FDA's new headquarters food research building at Beltsville, Maryland, nor to facilities at NIH or the Beltsville Agricultural Research Center, for which FDA reimburses the other agencies directly for expenses incurred in operating and maintaining the facilities provided for FDA. The rental costs do not include the special services for which FDA must pay GSA on a reimbursable fee-for-service basis, such as special guard services and the provision of around-the-clock heating and air conditioning where required for FDA's laboratory work.

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BUILDINGS AND FACILITIES

Summary of Program Estimates
(\$000)

	1993 <u>Actual</u>	1994 <u>Appropriation</u>	1994 <u>Current</u> <u>Estimate</u>	Increase or <u>Decrease</u>	1995 <u>Estimate</u>	Increase or <u>Decrease</u>
(\$000)	\$19,664	\$8,350	\$8,350	---	\$8,350	---

Justification: \$8,350,000 is requested to provide for the Agency's highest priority maintenance, repair and improvement projects.

This request will preserve the integrity of FDA facilities, reasonably ensure employee safety, and meet ever-changing program demands and technological developments. The Agency's ability to make and support sound scientific-regulatory decisions depends, to a great extent, on modern, well equipped, optimally functioning facilities.

Plan of Work: The total of \$8,350,000 requested will provide for the following projects in FY 1995:

Repair and Improvement of Existing Facilities

1. ORA, WEAC - General Repairs and Maintenance . . \$1,150,000
2. NCTR, Jefferson, AR - Miscellaneous Repairs
and Improvements 980,000
3. CFSAN, Gulf Coast Seafood Lab, Dauphin Island, AL
Pollution Control and
Miscellaneous Repairs and Improvements 290,000
4. ORA, Los Angeles, CA. - Asbestos Abatement
and HVAC Replacement 500,000
5. CDER, Headquarters, Rockville, MD
Research Center Modifications. 100,000
6. ORA, San Juan. - Replace Electrical and Water
Distribution Systems, Energy Efficient Lighting
System; Road Repairs; General Repairs and
Maintenance 930,000
7. ORA, Baltimore District Office, - Laboratory
Renovations and Fume Hood Replacement 750,000

8.	CBER, NIH, Building 29 - Feasibility, Cost Study and Program of Requirements	250,000
9.	ORA, Laboratory Fixtures for New Facilities	<u>3,400,000</u>
	TOTAL	\$8,350,000

FOOD AND COSMETICS**STATUS OF PROGRAM**

Activities of the Food and Cosmetics program are authorized under the FD&C Act, the Public Health Service Act, the Tea Importation Act, the Fair Packaging and Labeling Act, the Infant Formula Act, and several other federal statutes. These statutes, either in their entirety or in part, give FDA major responsibilities for assuring the safety, sanitation, wholesomeness and economic value of food and the safety and proper labeling of cosmetics available to U.S. consumers. These responsibilities cover imported as well as domestically produced products.

Current Activities. To meet these responsibilities, FDA:

1. Inspects establishments, collects samples, analyzes samples, and takes legal action, where necessary, in order to prevent domestically produced or imported foods which may be hazardous or insanitary from entering the market place.
2. Works cooperatively with state and local governments to assure the safety and wholesomeness of milk and milk products.
3. Works with NOAA to implement a jointly sponsored program designed to improve the safety, quality, and labeling of seafood available to American consumers.
4. Provides training and technical assistance to state and local governments on matters related to the design, implementation, and evaluation of retail food protection programs.
5. Prevents the introduction or transmission of communicable disease through the food and water supply of airlines, trains, boats or other components of the interstate transportation industry.
6. Assures the safety and proper use of food additives.
7. Maintains and improves the nutritional quality of the nation's food supply by ensuring that food products meet established nutrient requirements.
8. Conducts research to improve the speed and accuracy of methods for the detection and enumeration of foodborne biological hazards. This includes efforts to apply DNA technologies to improve systems for detecting and assessing the virulence of foodborne pathogens.

9. Develops more effective methods for assessing health hazards associated with infant formulas, and investigates the effects of processing and formulation on the nutrient quality of these products.
10. Develops and expands single compound and multi-residue methods for the analysis of pesticides and their metabolites in foods.
11. Conducts studies to determine the levels of occurrences and daily dietary intake of pesticides, PCBs, and other industrial chemicals, selected toxic elements, nutrients, and radionuclides.
12. Develops new or amends existing food standards and other regulations that are intended to assure the fair, accurate, and honest labeling of food products. Conducts research to develop or improve analytical methods required to more rapidly and accurately detect economic adulteration in foods.
13. Conducts toxicological research studies to determine the safety of cosmetics and cosmetic ingredients as well as develop data bases to more precisely quantify the health risks involved with their use.
14. Develops and improves analytical methodologies to identify and quantify any hazardous ingredients, dangerous additives, or chemical and microbial contaminants in cosmetic products.
15. Conducts inspections and sample analyses to determine that cosmetic production facilities are sanitary and that cosmetic products are prepared, packed, and held in accordance with good manufacturing practices.

Selected Examples of Recent Progress

1. Activities to Implement the Nutrition Labeling and Education Act

The Center for Food Safety and Applied Nutrition (CFSAN) continued work to implement requirements of the Nutrition Labeling and Education Act (NLEA) of 1990. Examples of these activities include:

Results of Labeling Survey - In May, the results of a nationwide survey were announced showing that more than 70% of approximately 2,000 food stores surveyed were voluntarily providing information about raw produce and fish. The voluntary participation in the site-of-sale labeling program satisfies the standard that FDA established under the NLEA requiring that at least 60% of all food stores take part, or the program becomes mandatory. The foods covered by the voluntary labeling program are 20 of each of

the top-selling raw fruits, vegetables and seafood. FDA will monitor national produce and seafood consumption data and update the list of the top 20 varieties of fruits, vegetables and seafood every two years. In 1994, another survey will be conducted to determine whether most food retailers continue to comply with the voluntary program.

Labeling Restaurant Menus - In June, FDA announced a proposal to require restaurant menus that contain health claims or nutrient content claims to meet some of the same requirements as food sold in grocery stores. The restaurant menus would need to provide a reasonable basis for making the claims. The proposed regulations would provide flexibility in deciding what constitutes a reasonable basis. For example, a restaurant could satisfy this requirement by using menus designed by recognized medical or dietary groups to promote better nutrition or health.

Food Labeling Questions and Answers - In August, FDA announced the availability of a booklet entitled, "Food Labeling, Questions and Answers" that addresses many questions concerning the regulations issued to implement NLEA. The Agency has received a large number of inquiries about the final rules and the booklet was prepared to respond generally to the most frequently asked questions.

2. Dietary Supplement Labeling Regulations/Activities

The FDA, in June 1993, proposed regulations governing nutrition labeling and nutrient content and health claims for all dietary supplements -- vitamins, minerals, amino acids and other similar nutritional substances. The proposal would require dietary supplement product labels to carry the same kinds of nutritional information as virtually all processed foods. Health claims would be permitted if FDA finds "significant scientific agreement" that the claims are valid. The NLEA established this standard for health claims on food labels and the same standard would apply to dietary supplement products. In addition, the Agency announced its intention to work with food and supplement manufacturers and scientists on additional health claims that could be permitted on labels. FDA published final dietary supplement labeling rules in December, 1993. Consumer access to dietary supplements will not be affected by these regulations, nor will prescriptions be needed to obtain any dietary supplement after the regulations become effective.

Sales of dietary supplements containing vitamins and minerals have increased dramatically during the past two decades. Dietary supplements are now readily obtainable at grocery stores, drug stores, health food stores, and specialty nutrition stores, as well as by mail order. It is estimated that in 1990 the sales of these products totaled near \$3 billion. At the same time that dietary supplement use has been growing, several significant

illness outbreaks associated with these products in recent years have increased concerns regarding their safety. In 1989, for instance, at least 1,500 cases of eosinophilia myalgia syndrome (EMS), including 38 deaths, were associated with supplements containing L-tryptophan. Also, within the last year there have been reports of serious illnesses associated with the use of certain herbal and other botanical supplements.

In July 1993, FDA issued the report "Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace". The report documents the pervasiveness of unsubstantiated claims currently being made for dietary supplements in the U. S. marketplace and reviews health hazards associated with dietary supplements. Roughly 80 percent of the dietary supplement marketplace consists of vitamins and minerals that are marketed at reasonable potencies and make no unsubstantiated health claims. The conclusions of this report apply to the other 20 percent of the marketplace - those products that present safety concerns or make unsubstantiated claims.

In November 1993, FDA initiated a public conference on "Antioxidant Vitamins and Cancer and Cardiovascular Disease" at the National Academy of Sciences. Co-sponsored by other Federal and private health organizations, the purpose of the conference was to review and summarize the scientific information available for foods, including dietary supplements, on the association between the antioxidant vitamins and cancer and antioxidant vitamins and cardiovascular disease.

3. Hazard Analysis and Critical Control Point (HACCP) Regulations

In 1993, CFSAN worked to develop proposed mandatory HACCP regulations for seafood products. The FDA is proposing these regulations because a HACCP-based system of preventive controls is thought to be the most effective and efficient way to ensure that food products are safe. Under a HACCP system, food processors and handlers would evaluate the kinds of hazards that could affect their products, institute controls necessary to keep these hazards from occurring, monitor the performance of these controls, and maintain records of this monitoring for FDA inspection and auditing. FDA is proposing mandatory HACCP regulations at this time for the following reasons:

- a considerable amount of work in developing HACCP systems for seafood has already been done by states, academia, and the Federal Government.
- seafood industry representatives have requested that the Federal Government initiate a mandatory HACCP-type system.

- a mandated HACCP system would provide enhanced consumer confidence in seafood products.
- a nationally mandated HACCP-type system appears to be a prerequisite for continued access to world markets.

Publication of the proposed regulations is expected early in 1994.

4. Folic Acid

In early October, the FDA proposed to amend the food additive regulations to permit folic acid, a B-vitamin, to be added to flour, breads and other grain products to lower the risk of neural tube birth defects. The 1990 amendments (NLEA) required that FDA evaluate 10 nutrient-disease relationships with respect to their appropriateness for health claims. The relationship of folic acid to neural tube birth defects was one of the claims to be evaluated.

In September of 1992, based on reviews of existing and newly available scientific data, the PHS recommended that all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 milligrams of folic acid per day. This level of daily intake of folic acid was recommended as a means of reducing spina bifida and anencephaly in babies. About 2,500 live-birth cases of spina bifida and anencephaly occur each year in the United States. In spina bifida, the backbone does not fully form around the nerves on the spinal cord. The spinal cord is exposed and may be damaged when the child is born, sometimes resulting in paralysis. Infants and children with spina bifida may require a series of operations and other treatments, and most grow to adulthood with varying degrees of disability. In anencephaly, the child is born with a severe malformation of its brain and cannot survive.

The proposed regulation is designed to provide for a level of folate intake which will reduce the risk of neural tube birth defects while avoiding problems that can result from over consumption of this vitamin. Specifically, the regulation would require manufacturers to add folic acid to enriched flours, breads, rolls, buns, corn grits, corn meal, farina, rice, macaroni and noodle products. Also, labeling on foods that are good sources of folate (e.g., citrus fruits and dark green leafy vegetables) and dietary supplements containing folic acid will be permitted to state that daily consumption of the vitamin by women of child-bearing age may reduce the risk of neural tube defects in their offspring.

5. Advances in Analytical Methodologies

Applications of DNA Technology - FDA continued efforts to improve the effectiveness of its field surveillance activities through applications of DNA technology. This year it successfully transferred polymerase chain reaction (PCR) technology for detecting *Vibrio cholerae* to field laboratories. PCR methods for detecting other foodborne pathogens will be transferred to field laboratories as they are developed. These methods, which are faster and more accurate than the classical microanalytical methods, will permit the Agency to expedite the routine surveillance of food products for microbial pathogens.

Other applications of DNA technology included the development a PCR method for the rapid detection of *E. coli* 0157:H7 and a DNA fingerprinting method for determining the differences between the various isolates of this pathogen. Earlier this year, more than 500 people in the Northwest (from Washington, Idaho, California and Nevada) had laboratory confirmed cases of *E. coli* 0157:H7 infections. These infections were traced mainly to the ingestion of undercooked hamburger patties. Using these newly developed technologies, FDA was able to help the U. S. Department of Agriculture (USDA) and Centers for Disease Control (CDC) identify isolates of the pathogens from various outbreaks, verify that they were different, and rapidly confirm the source of the contamination.

FDA developed DNA fingerprinting technology which permitted it to demonstrate similarities between clinical isolates, in-plant isolates, and final product isolates of *Salmonella tennessee*. This method was particularly helpful in permitting the Agency to rapidly confirm *S. tennessee* as the pathogen in a soy based infant formula which caused salmonellosis in two Canadian infants. As a result, the Agency was able to quickly initiate a series of recalls to remove from the market place contaminated soy based infant formula and other products spray-dried or packaged at the Maple Island food processing plant in Wanamingo, Minn.

DNA fingerprinting technology was also used to demonstrate that the unusual strain of *Vibrio cholerae* non-01, which is responsible for the current cholera pandemic, is actually a mutant of an 01 strain that has been associated with Asiatic cholera. Generally, non-01 serotypes have not been associated with severe forms of the disease and are frequently isolated from the estuarine environment. These findings will have to be taken into account in conducting food surveillance and sample analysis activities.

FDA Collaborates on Manual of Methods of Analysis for Nutrition Labeling - In 1990, the Nutrition Labeling and Education Act (NLEA) mandated, for the first time, labels containing information about nutritional content of nearly all processed foods. To accomplish this task, analytical data must be generated for hundreds of thousands of foods. To address the analytical demands of NLEA, the Association of Official Analytical Chemists (AOAC) International formed the Task Force on Methods for Nutrient Labeling Analyses, which identified and documented the availability of methods for nutritional analysis. This task force was comprised of representatives from FDA, academia, private companies, and trade associations. The task force assessed AOAC Official Methods relative to the labeling regulations and identified and recommended further study for nutrients with inadequate methodology. The "Manual of Methods of Analysis for Nutrition Labeling" supports and expands the efforts of the task force and provides guidance for the proper selection of methods for nutrient labeling. All of the AOAC Official Methods acceptable for use in nutrition labeling are contained in this manual. Thus, the most current information available on methods for nutrition labeling is assembled in this manual.

Potassium Bromate in Bakery Products - During 1993, FDA developed analytical methodology for determining potassium bromate in bakery products. Use of this method enabled the generation of survey data for estimation of human exposure to this dough conditioner. The methodology and residue data are providing the information that is essential to the development of a risk management decision and regulatory proposal concerning the continued use of potassium bromate in flour and bakery products.

Monosodium Glutamate (MSG) as Glutamic Acid - A method for the determination of MSG as glutamic acid has been developed and two High Performance Liquid Chromatography (HPLC) methods and an industry used enzymatic method have been compared and partially validated for possible regulatory enforcement purposes. Valuable occurrence data on MSG levels in flavors and other foods have also been provided to assist in the development and enforcement of MSG labeling proposals.

6. Management Improvements and Initiatives

In FY 1993, CFSAN made progress on several significant management improvements and initiatives. The following are examples of these activities:

Reorganization of FDA's Center for Food Safety and Applied Nutrition - In November 1992, the Center for Food Safety and Applied Nutrition (CFSAN) announced a reorganization of the Center's program structure. The new structure integrates policy, regulatory and scientific specialists together into product oriented offices designed around their areas of expertise. Under

the new organization, the Center Director is supported by two Deputies -- a Deputy Director for Programs and a Deputy Director for Systems and Support. The Deputy Director for Programs supervises the operation of seven new specialized policy/science offices created to meet specific needs of the major CFSAN program areas. The Deputy Director for Systems and Support manages a wide range of administrative and support staffs in four new offices. In addition, an Office of Policy, Planning and Strategic Initiatives was established to manage cross-cutting policy issues, long range initiatives and strategic planning for the Center. The new organization structure positions FDA for future challenges in the Food and Cosmetic Program and ensures that program priorities appropriately reflect public health priorities and are commensurate with available resources.

Strategic Plan for FDA's Food and Cosmetic Program - In 1993, CFSAN began development of a Strategic Plan for the Food and Cosmetic Program. The purpose of the plan is to identify challenges to the success of the program and to delineate its key goals and objectives to take it into the 21st century. The strategic plan will incorporate big and small management initiatives in the Center and sets out to redesign and improve program and administrative activities and/or devise new ways of doing business that will improve performance, customer service, and/or cost-effectiveness. Examples of these initiatives in programs include the development of Hazard Analysis and Critical Control Point (HACCP) Regulations and efforts to streamline the premarket evaluation system for food and color additive petitions. Management initiatives include the goal to re-invent, to the extent locally possible, personnel and management practices, operational processes, and automated information systems to create a Center that is more efficient and cost effective. The plan will:

- focus program resources most effectively on the most important challenges
- communicate the major goals and priorities to program personnel and external constituencies
- provide long term perspective to guide development of annual tactical plans
- provide long term perspective to guide program investments and formulation of budget requests.

Streamline the Premarket Evaluation System for Food and Color Additive Petitions - There have been several management improvements and ongoing initiatives in the CFSAN premarket evaluation program. The Center's reorganization in November 1992 established the Office of Premarket Approval. This Office provides a centralized, coordinated focal point for food and color additive petition review. It includes much of the needed scientific support for premarket evaluations within the office, facilitating a team approach to petition review. This new

structure enables better management of petitions submitted by industry, improving the quality of the review. During the year, several work groups examined the premarket evaluation system to identify areas in the petition review process where new management approaches might enhance operations. In September 1993, a 2 day go-away was held to discuss ways to implement some of these new approaches to improve the effectiveness of this program. The goal of the program is to streamline the premarket evaluation system for food and color additive petitions while maintaining the integrity and credibility of the safety review process. Also, in response to the Government Performance and Results Act of 1993 and the findings of the National Performance Review, work has started to develop performance measures and performance targets for the premarket review program. These performance measures and targets will be used to formulate a performance-based FY 96 budget plan.

7. Regulatory Actions

In FY 1993, FDA identified and took regulatory action against numerous potentially hazardous or otherwise violative products. For instance, the Agency initiated 47 seizure actions against food/cosmetic products; 2 of these were "mass" seizures involving multiple food lots. There were a total of 655 recall actions against foods ; 6 against cosmetics . Of the food recalls, 434 (66.2%) were due to microbiological hazards or sanitation problems, 100 (15.3%) were due to violations of food and color additive regulations, 59 (9.0%) were due to food economics violations, 57 (8.7%) were for chemical contaminant problems, and 5 (0.8%) were due to natural toxins. In addition, the Agency initiated prosecutions against 2 firms and injunctions against 7 food producers.

FDA uses product detention as the primary regulatory mechanism for preventing violative imported products from entering the country. During FY 1992, 28,443 detention actions were initiated. Of this total 27,442 were against foods, 334 were against dietary supplements including vitamins and minerals, and 666 were against cosmetic products.

8. Pesticides and Chemical Contaminants

Pesticide Surveillance Report - In September 1993, FDA published its sixth annual report that describes FDA's pesticide residue monitoring program and presents findings from that monitoring for FY 92. The report includes the three approaches FDA uses to carry out its pesticide program: regulatory monitoring, incidence/level monitoring, and the Total Diet Study.

Under monitoring designed to enforce tolerances set by the Environmental Protection Agency (EPA), FDA analyzed in FY 92 a total of 16,428 samples of domestically produced food from all 50

states and Puerto Rico and imported food from 94 countries. Of these, 15,370 were surveillance samples, collected when there is no evidence that a shipment might contain illegal pesticide residues. No pesticide residues were found in 65% of the 7,548 domestic surveillance samples, less than 1% had residues that were over EPA tolerances, and less than 1% had residues for which there was no established tolerance for that particular pesticide/commodity. Of the 7,822 import surveillance samples, 66% had no residues detected, less than 1% had residues that were over tolerance, and 3% had residues for which there was no tolerance. Violative samples were found in 1.1% of the domestic surveillance samples and 3.8% of the import surveillance samples.

Under incidence/level monitoring, 2 projects were carried out in FY 92. In the continuation of an aquaculture survey initiated in 1990, 206 samples of shell- and finfish were analyzed for selected, environmentally persistent pesticides. Low levels of chlorinated pesticide residues were found in about 65% of the samples but none exceeded EPA tolerances or FDA action levels. A survey of pasteurized whole milk from U.S. metropolitan areas found that detectable levels of residues of pesticides were present in about 48% of the 558 samples. Most of the pesticides detected are no longer registered for food use but because of past agriculture use and because of their persistence in the environment, they are still present at low levels in some foods of animal origin.

In the Total Diet Study, which measures pesticide residues in foods as consumed, 4,914 food items representing the diets of U.S. consumers were analyzed. Of the more than 200 chemicals that can be determined by the analytical methods used, 70 were found in the foods analyzed. As in previous years, the levels of estimated dietary intakes of the pesticides found were generally well below established standards.

In other pesticide program activity in FY 92, 22 states supplied pesticide residue data via the "Foodcontam" database, which is a compilation of state-collected residue data under contract with Mississippi State University. Of 14,900 samples represented, residue findings for 1.1% were classified as significant. This is the same as FDA's domestic surveillance violation rate.

The findings of FDA's pesticide surveillance program for FY 92 are consistent with those given in previous reports of FDA regulatory monitoring.

Special Surveillance Assignments - FDA began conducting its third and fourth Incidence Level and Monitoring assignments to determine pesticide residues in fruits and vegetables as sold in the fresh market. Approximately 1600 samples of both domestic and imported apples and rice will be analyzed. The surveys follow similar assignments conducted in FY 1993 on pears and tomatoes. The 1993 surveys are currently being evaluated in CFSAN. The surveys are being conducted to counteract criticism of FDA's traditional compliance sampling programs of fresh fruit and vegetables as not being statistically significant.

FDA Proposes New Limits for Contaminants in Bottled Water and Standard Bottled Water Regulations - FDA is responsible for overseeing the safety of bottled water which, like other foods, must be processed, packaged, shipped, and stored in a safe and sanitary manner and accurately labeled. This function includes setting maximum limits for chemical, bacteriological, radiological and physical contaminants that may be present. During 1993, one final rule and five proposed rules concerning regulation of bottled water were published in the Federal Register. On January 5, 1993, a final rule that established maximum allowable levels for 7 volatile organic chemicals (e.g., benzene) and two proposals to establish new or revised allowable levels for 41 additional chemical contaminants (e.g., lead) in the bottled water quality standard were published. Also on January 5, 1993, a proposal to establish a standard of identity for bottled water containing definitions for various types of water (artesian, distilled, purified, mineral, spring, and well) that are bottled was published. FDA proposed these standard definitions because they are frequently used on the labels of bottled water but have had no standard meanings. This proposal also proposed to make bottled mineral water subject to the bottled water quality standard. On August 4 and October 6, 1993, respectively, a proposal to establish allowable levels for 24 additional chemical contaminants in bottled water and a proposal to amend the microbiological quality standard for total coliforms in bottled water were published.

Should these proposals become final, bottled water will have to comply with an identity standard for bottled water and with maximum allowable levels for 81 chemical contaminants and the absence of total coliforms (in addition to existing requirements for physical and radiological contaminants) in the quality standard for bottled water.

Dietary Lead Exposure - FDA is continuing efforts to identify human lead exposure related to the following products under its jurisdiction: food, lead-soldered cans, calcium dietary supplements, food additives, bottled water, wines, wine bottle seals, ceramic ware and other foodware. The effort is directed toward determining the relative contribution of each source to overall exposure and taking steps to reduce or eliminate lead exposure from these sources. These activities are important because when absorbed into the bloodstream, lead can cause widespread injury to the body, particularly to the central and peripheral nervous system, red blood cells, and the renal system. The following are FY 93 regulatory accomplishments:

November 25, 1992 : FDA proposed to prohibit the use of tin-coated lead foil capsules on wine bottles. Proposal was based on recent evidence that lead from the capsules becomes a component of food and, therefore, the capsules are unauthorized food additives.

January 5, 1993 : FDA proposed to reduce the allowable level for lead in the bottled water quality standard from 50 ppb to 5 ppb.

April 1, 1993 : FDA published a notice announcing emergency action levels for lead in food packed in lead-soldered cans. This is an interim measure to address some serious lead exposures from foods packed in lead-soldered cans until the prohibition on lead-soldered food containers can be finalized. [Note that domestic can manufacturers ceased producing lead soldered cans in late 1991.]

June 21, 1993 : FDA proposed to prohibit the use of lead solder in cans that contain food.

July 15, 1993 : FDA published notice providing an opportunity for comment on the revised Food Chemicals Codex (FCC) policy to reduce the lead limits (as well as the heavy metals limit) to the lowest levels feasible for FCC substances. The Committee also solicited suggestions for lower limits for incorporation in food ingredient monographs.

August 1993: FDA issued a guidance document for lead in shellfish. This is one of a number of guidance documents to assist state and local officials in determining the public health significance of contaminants in shellfish.

Advisories for Food Products Containing Vomitoxin - FDA has issued updated advisories for certain human food and animal feed products containing deoxynivalenol (DON). Deoxynivalenol, commonly called vomitoxin, is a natural toxin produced by several molds of the genus *Fusarium*, especially *F. graminearum*, which is a common contaminant of several grains, including wheat, corn, barley, and rye. *F. graminearum* thrives in cool, wet conditions

such as occur in the mid-west grain producing states in some years, e.g. upper mid-west in spring and summer of 1993. The fungus causes pink scab disease in wheat. DON has been associated with a number of adverse health effects in humans and animals. FDA's new advisories provide guidance to state agricultural officials as well as to the food, feed and grain industries about what levels of DON can be present in finished wheat products for humans and grain and grain by-products intended for animal feed. These levels supersede 1982 FDA advisories. Vomitoxin does not represent a threat to public health among the general population. However, it can sometimes produce acute temporary nausea and vomiting in humans and animals.

FDA's new advisories set the level for vomitoxin in finished wheat products intended for human consumption such as flour, bran and germ, at 1 part per million (ppm). This level was set by CFSAN based on its evaluation of the latest available toxicological evaluations. Levels have not been set for unprocessed products because milling processes used to produce flour substantially reduce DON levels, to varying degrees. It is not possible to avoid the presence of at least some vomitoxin in wheat. FDA's Center for Veterinary Medicine has also evaluated this data and has issued advisories for the following: Animal feed use of grains and grain products: 10 ppm for ruminating beef and feedlot cattle older than 4 months and for chickens not to exceed 50% of the diets; 5 ppm for swine not to exceed 20 % of the diet; and 5 ppm for all other animals not to exceed 40 % of the diets.

FDA also analyzed 600 wheat and barley samples collected by USDA from around the country to assess the extent of the 1993 outbreak. FDA is working with the USDA and state authorities to monitor this situation, and will take appropriate regulatory action on a case-by-case basis to prevent grain products with excessive levels of vomitoxin from reaching the market.

Guidance Documents on Elemental Contaminants - Final guidance documents for arsenic, cadmium, chromium, lead and nickel levels in seafood were completed and published in 1993 by CFSAN's Office of Seafood. Also started to draft guidance documents for aluminum, domoic acid, selenium, zinc and methylmercury in 1993.

9. Consumer Education

Seafood Hotline - FDA established a Seafood Hotline in FY 1993 to answer questions on microbiological safety (including handling and storage), labeling, nutrition, economic fraud and chemical contaminants. A toll free number(1-800-FDA-4010) provides access to consumers from all 50 states and Puerto Rico. The Hotline has completed its first year with 20,858 calls from the public.

The Hotline is accessible 24 hours a day for consumers to listen to seafood messages in English or Spanish and to order publications by fax or mail. During the hours of 12 noon to 4 p.m. Eastern time Monday through Friday, consumers may speak directly to a public affairs specialist for specific questions. The Hotline has been a primary means of disseminating health alerts to high risk individuals which is a part of HHS's "Healthy People 2000" goals to decrease foodborne illness. Via the hotline, 12,439 publications have been mailed, 1180 publications have been transmitted by the automated fax machine and callers have listened to 16,725 recorded seafood messages. Because the system has been designed to anticipate the needs of the consumer and can be changed as new issues arise, the automated system has been able to service 75% of the callers without the assistance of live operators. The Hotline has also helped to identify problems in labeling, regulatory issues, research, recalls and complaint handling within the seafood industry.

Seafood Safety Brochures - In addition to directly assisting consumers by providing them with reliable seafood information, the Hotline has produced information that will guide FDA in developing educational and informational materials that the public wants and needs. Examples include publication of four brochures on seafood safety specifically targeted to people who have liver disease, diabetes mellitus, immune disorders, or gastrointestinal disorders.

10. Labeling of Foods Developed Through Genetic Engineering

On April 28, 1993, FDA published a Federal Register notice requesting data and information on issues related to labeling of foods derived from plants developed through genetic engineering. The notice responds to public comments requesting such labeling as a result of FDA's May 1992, policy statement on food derived from new plant varieties. The notice provided 90 days for comments to provide FDA with more information on definitions of genetic engineering, how genetically engineered plants differ from plants bred using other techniques, and associated labeling issues. The notice also said that the agency expects to hold a public meeting on labeling issues in the future based on information received through the comments on this notice.

11. 1993 "Redbook" Availability

CFSAN has revised the 1982 "Redbook", Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food". The "Redbook" is intended to provide guidance to petitioners regarding criteria used by the agency for toxicological safety assessments of direct food additives, color additives, and generally recognized as safe (GRAS) substances. This revision takes into account developments in toxicological testing, as well as comments received from the scientific

community and the public on the earlier version. It contains new or significantly expanded sections on metabolism and pharmacokinetics, immunotoxicology, neurobehavioral toxicology, alternatives to whole animal testing, unique and specialized additives, pathology considerations, statistical considerations, human testing, epidemiological studies and risk assessment. The 1993 draft is available from CFSAN's Office of Premarket Approval and a notice of its availability and request for comments was published in the Federal Register.

12. Seafood Experts Conduct Tuna Workshop and Fact-Finding Mission in Thailand

A team of FDA seafood experts traveled to Thailand at that government's invitation to run an intensive, two-week workshop on FDA's standards of decomposition and related topics for tuna. The workshop was attended by some 50 participants including representatives from the Thai industry, government, laboratory personnel and other interested parties. The tuna industry is a big part of the Thai economy and the United States is a major market for these products. The Thai government was concerned that the FDA was going to impose a detention on seafood products because of ongoing problems with decomposed tuna being canned and shipped out of Thailand. The Thai Department of Fisheries is working to educate those involved in seafood production, transportation, laboratory analyses, and marketing, and plan to submit a proposal to FDA detailing what Thai companies plan to do to end the ongoing problems with decomposition.

The team of seafood experts also conducted a fact-finding mission to 11 of the country's 18,000 shrimp farms. The regulators were concerned about possible widespread usage of chloramphenicol, an antibiotic that is classified by the U. S. as a carcinogen. The delegation also visited five shrimp processing plants and found that all were operating under good manufacturing practices and were applying HACCP concepts.

13. FDA Issued Recalls/Warnings /Guidance

In 1993, FDA conducted recalls and issued warnings/guidance to the public about certain food products. The following are some examples of these activities:

Recall of Products at Maple Island Inc. Processing Plant - The FDA on June 29 announced the recall of products dried and/or packaged at Maple Island Inc., a food processing plant at Wanamingo, Minn., because of *Salmonella* contamination. Maple Island Inc. processes dry soy- and milk-based infant formulas and other powdered products for 11 companies as well as for sale under its own labels. Recalls requested by FDA included powdered infant formulas, medical foods, whole milk powder, nonfat dry

milk, ice cream mixes, powdered drink for meal replacement and a powdered supplement for use by lactating or pregnant women. All of the products under recall have been spray dried and/or packaged in the Wanamingo plant since November 4, 1992, the earliest date to which FDA sampling traced the *Salmonella* contamination. FDA initiated investigation of Maple Island Inc. after Canadian authorities reported that two infants who had consumed Soy-lac formula spray-dried at the Wanamingo plant had developed salmonellosis, a disease that can be life-threatening for very young children. After initial FDA and company sampling identified contamination by a strain of bacteria called *Salmonella tennessee*, the plant voluntarily stopped its drying operations and undertook a major cleanup of the facility. Following additional FDA sampling, Maple Island Inc. shut down its packing operations and initiated its recalls. FDA focused its efforts on infant formulas and medical foods because infants and the elderly are most vulnerable to salmonellosis. In addition to Maple Island Inc., FDA informed four other firms whose products had been processed at the Wanamingo plant of the recall notice. All foreign distributors of these products were advised of this recall. FDA is not aware of any illnesses caused in the United States by the products under recall.

FDA Warning on Chaparral - The FDA issued a warning to the public in December, 1992 against consuming the herbal product chaparral because it has been associated with acute toxic hepatitis. Chaparral has been linked to severe liver problems in at least four people in this country. The warning stated that people with underlying health problems may be particularly at risk if they consume this product. Chaparral is derived from the ground leaves of the creosote bush which grows in the deserts of the American Southwest. The herb is used in teas, capsules, and tablet preparations that purport to "cleanse" the blood stream, delay the aging process and treat various skin conditions. FDA is continuing its investigation to obtain more information about the product and the extent and patterns of use. The Agency will take appropriate action when more information is available.

Retail Cooking of Ground Beef - The FDA issued an interim guidance document recommending that all federal, state and local food regulatory officials change the internal cooking temperature required for ground beef from the current 60 C (140 F) to 68.3 C (155 F). This recommendation is to be distributed to the restaurant industry.

This action was deemed necessary following a large and serious foodborne illness outbreak in the western states associated with inadequately cooked ground beef. Laboratory confirmed reports indicate that the raw frozen beef patties supplied to a chain of fast food restaurants contained *Escherichia coli* O157:H7 (also called enterohemorrhagic *E. coli* or EHEC). This organism typically causes bloody diarrhea. Young children and the elderly

may develop serious complications (hemolytic uremic syndrome [HUS] or thrombocytopenic purpura [TTP] respectively) which may lead to kidney failure, and in some cases, death.

FDA Warning on Potential hazard from Unrefrigerated Garlic-, Spice-in-Oil Mixes - FDA issued a warning to consumers about proper storage of homemade and commercially prepared chopped garlic-in-oil, garlic-in-butter and garlic-in-margarine mixes. This warning states that such mixes, especially those prepared fresh at home, should be kept refrigerated. Left at room temperature, the mixes may cause potentially fatal botulism food poisoning. FDA also cautioned dietitians and food service workers who plan or prepare meals at hospitals, nursing homes and other institutions about this matter. FDA issued a similar warning in March 1989, when three persons were hospitalized in New York with botulism poisoning after consuming a commercially prepared garlic-in-oil mix that had been stored at room temperature despite a "Keep Refrigerated" statement on the label. As a result of that incident, FDA ordered manufacturers to stop making garlic-in-oil mixes that rely solely upon refrigeration for safety. FDA now requires that commercial mixes contain specific levels of microbial inhibitors, usually acidifying agents such as phosphoric or citric acid. The presence of these additives in commercially prepared garlic products is disclosed on their labels. FDA recommends that consumers not prepare any homemade spice-in-oil, -margarine or -butter recipes for extended storage because the protective additives used in commercial mixes are not generally available for homemade products. Consumers are urged to refrigerate all such products and to dispose immediately of any products suspected to be spoiled or to have been stored unrefrigerated. *Clostridium botulinum* bacteria are widespread in the environment and may be found on various kinds of produce, including garlic, but their spores are harmless in an oxygen environment. However, in an anaerobic (oxygen-free), low-acid environment, the spores can proliferate and produce the toxin that causes botulism. FDA studies have shown that garlic-in-oil mixtures can support *Clostridium* bacterial growth and toxin production even when very few spores are present.

HUMAN DRUGS**STATUS OF PROGRAM**

The Human Drugs program is responsible for assuring that all drug products used for the prevention, diagnosis, and treatment of disease in the U.S. are safe and effective, properly labeled, and that information on proper use is available to all users.

Current Activities. To accomplish these responsibilities, FDA:

1. Evaluates the safety and effectiveness of drugs before permitting marketing, and monitors and audits preclinical and clinical testing of new drugs, and conducts pre-approval inspections of drugs subject to applications to assure compliance with current good manufacturing practices, application commitments, and data integrity.
2. Monitors the short and long-term effects of marketed drugs, including their utilization, to discover potential safety problems and establish a scientific basis for regulatory actions.
3. Develops and publishes monographs for monitoring over-the-counter drug products on the market.
4. Monitors the quality of marketed products through surveillance and compliance actions; conducts inspections of manufacturing establishments to ensure compliance with established regulations and good manufacturing practices and removes those products from the marketplace not meeting standards, including fraudulent health products.
5. Conducts research to establish product standards and develops analytical methodology and improved test methods.
6. Monitors product advertisements and promotional labeling and enforces requirements for accurate and balanced representations.
7. Maintains the integrity of the distribution system for marketed prescription drugs by investigating and taking corrective action against individuals or parties that divert, or contribute to the diversion of, prescription drug products and prescription drug samples.

Selected Examples of Recent Progress:

1. Generic Drugs

In 1993, 32 products were approved as generics for the first time. Many of these approvals represented the first time a generic drug was available for the brand name product, and some represented the first time availability for certain strengths and dosage forms. Some examples include Gemfibrozil (generic for Lopid, Parke Davis), Clotrimazole cream (generic for Lotrimin, Schering), Miconazole nitrate (generic for Monistat, R. W. Johnson), Diltiazem HCl SR (generic for Cardizem SR, Merrell Dow), Metoprolol (generic for Lopressor, Ciba Geigy), Alprazolam (generic for Xanax, Upjohn Company), Naproxen Sodium (generic for Anaprox, Syntex), and Nadolol (Corgard, Squibb). An application for cimetidine tablets (generic for Tagamet) was tentatively approved. This tentative approval may make it possible for the generic version to be marketed when the patent expires in May 1994.

FDA issued 17 new guidances for in vivo bioequivalence studies and in vitro dissolution testing in 1993. On September 9, 1993, a guidance entitled, "Oral Extended (Controlled) Release Dosage Forms In Vivo Bioequivalence and In Vitro Dissolution Testing" was issued. While most guidance relate to specific products, this dosage form guidance is important because it impacts on many different products. This guide proposes testing recommendations for Abbreviated New Drug Application (ANDA) applicants for extended release products administered orally. The active ingredients in these products, unlike those that release immediately after ingestion, release in a slow and controlled manner which allows reduced dosage frequency.

The Generic Drugs Advisory Committee (GDAC) met twice in 1993. At its February 1993 meeting, the GDAC encouraged the Office of Generic Drugs to develop clinical trial designs and statistical methods for evaluating drug bioequivalence in individual subjects. This represents a change from the Office's former methods which average data from several study participants ("average bioequivalence"). The Office of Generic Drugs is assessing the new statistical approaches.

At the September 1993 meeting, the GDAC considered in vivo bioequivalence methods for albuterol metered dose inhalers. The Committee recommended the use of pivotal bronchoprovocation studies as well as supportive bronchodilation studies for bioequivalence studies for metered dose inhalers. The Committee also discussed the documentation requirements for bioequivalence of solution/device aerosol products for oral inhalation and nasal delivery. For those oral inhalation products in which the valve and actuator are the same as the innovator product and excipients are "essentially the same," bioequivalence may be documented by

in vitro methods only. If the devices are different, both in vitro and in vivo studies would be required, whether or not the excipients are "essentially the same." The Committee voted against the use of in vitro testing for products in which the delivery device differs from the listed reference product. For nasal solutions with a metering device, the Committee felt that comparative in vitro tests alone are acceptable to document bioequivalence.

2. Acquired Immune Deficiency Syndrome (AIDS)

FDA is responsible for the approval of safe and effective drugs used in the treatment of human immunodeficiency virus (HIV) infection, AIDS, and AIDS-associated opportunistic diseases. FDA is also responsible for regulating investigational new drug applications (INDs).

Special emphasis continues to be placed on ensuring the most timely and efficient premarketing review possible of drug products that offer promise for diagnosing, treating, or preventing HIV and HIV-related diseases. In 1993, FDA made two new drugs available for the treatment of AIDS patients. A New Drug Application (NDA) was approved for atovaquone (trade name, Mepron), a drug used for the treatment of mild to moderate *Pneumocystis carinii* pneumonia (PCP) in patients who are intolerant of trimethoprim-sulfamethoxazole, the standard therapy. PCP is one of the most common opportunistic infections afflicting AIDS patients, whose depleted immune systems can make them highly vulnerable to such infections. Atovaquone had previously (in November 1991) been made available to patients under the treatment investigational new drug program.

A second drug was made available for expanded investigational use. The AIDS drug d4T (stavudine) was the first drug made available under FDA's "parallel track" policy, under which promising new drugs for treating AIDS and other life-threatening diseases are made more widely available to people who are unable to take standard therapy and unable to participate in controlled studies. This parallel track study enrolled patients who had experienced serious side effects from AZT or ddI or whose conditions had worsened while those drugs were being taken.

3. Research Efforts

Focused regulatory research at FDA continues to be an integral part of the drug review and development processes. The drug review process identifies needs for pre-clinical and clinical data that could facilitate and speed the development of potential therapeutic entities and their availability to patients.

The overall goal is to provide up-to-date science and flexible laboratory capabilities to react to new and emerging issues and problems while maintaining a set of core projects of continuing interest and importance. As drugs enter into pre-clinical and clinical testing and product applications are filed with the Agency, priorities change quickly.

Drug metabolism phenomena and drug-to-drug interactions are gaining more and more emphasis as a major regulatory concern. Because it is not possible to screen all possible combinations in clinical studies, many of these interactions are first discovered as adverse drug reactions in our postmarketing surveillance activities. FDA's Division of Clinical Pharmacology is pursuing the development and validation of in-vitro screening systems using human liver material which greatly expand the efficiency of pre-market testing and can help identify problematic and potentially life-threatening interactions before widespread patient use.

FDA's Division of Research and Testing performs drug quality assurance testing mandated by federal regulations and compendial specifications. In addition, this unit is actively conducting research which aims to minimize the use of animals in drug development and quality assurance testing.

The Agency's Division of Drug Analysis in St. Louis, Missouri, is the major focal point for the evaluation and validation of analytical methods which are submitted in conjunction with New Drug Applications.

In addition to laboratory-based research, advances in pharmacokinetic/pharmacodynamic modeling and data analysis techniques (pharmacometric research) serve to maximize the likely benefit of a drug while minimizing risk to a patient by expanding the use of clinical data, including identification of patient characteristics that optimize drug effects or predispose a patient to adverse effects. FDA has recruited staff with expertise in this area, and has initiated an internal training and research program.

FDA continues to be collaboratively involved in extramural clinical pharmacology research activities with other federal agencies, Johns Hopkins University and Georgetown University. These projects include evaluation of clinical performance criteria for metered-dose inhalers which are extremely important "first-line" dosage forms in the treatment of respiratory disease, pharmacodynamic correlations for the anti-AIDS drugs AZT and DHPG, and digoxin bioavailability and early clinical studies of anti-cancer drugs.

4. The New Drug Review Process

In 1993, FDA approved 82 New Drug Applications (NDAs). Twenty-six of these approvals were for new molecular entities (NMEs), drugs distinctly different in structure from those already on the market. Thirteen of these NMEs were in the priority classification (drugs that offer an important therapeutic gain); and five of the drugs were orphan drugs (medications developed under a special program to assist manufacturers of products where the potential patient population is otherwise too small for drug research, development and marketing to be profitable).

Several of the newly approved NMEs represent important breakthroughs for patients: Taxol (paclitaxel) - for the treatment of metastatic carcinoma of the ovary; Felbatol (felbamate) - for the control of certain epileptic seizures in adults and a rare form of epilepsy in children - the first drug approved for epilepsy in 15 years; and Cognex (tacrine hydrochloride) - the first drug ever approved to treat the symptoms of Alzheimer's disease.

Other significant approvals included the approval of Leustatin (cladribine), a one-treatment intravenous drug for hairy cell leukemia, a rare, often fatal cancer of the blood and bone marrow. The U.S. approval was the first of its type in the world. FDA also approved Orlaam (levo-alpha-acetylmethadol hydrochloride) for the treatment of narcotic addiction. Before this approval, methadone was the only other drug approved for treatment of patients with narcotic addiction. Flumadine (rimantadine HCl), an oral flu drug, was approved for the treatment of influenza A, the most serious form of flu, in both children and adults.

The median review time for all NDAs was 26.8 months. Six drugs were approved in less than 12 months.

FDA views computer technology as a promising way of making the new drug application review process more efficient. As such, FDA is committed to continuing to explore the use of automated technology via the CANDA program and is both educating and encouraging its own staff and urging the industry to accelerate their efforts in this area so that by FY 1995 virtually all submissions to the Agency will be either full CANDAs or have major automated components. From FDA's experience with CANDAs, it has been found that CANDAs have clearly facilitated FDA reviewer access to submission information; significantly improved communications between sponsors and the FDA; enabled better sponsor understanding of the review process; and, most importantly, enhanced the quality of the NDA review. In 1993, FDA received six CANDAs and approved five. Of that total, three were New Molecular Entities (NMEs).

5. New Drug Regulations and Policies

Between October 1992 when the Prescription Drug User Fee Act of 1992 (PDUFA) was passed and July 2, 1993 when FDA obtained its supplemental appropriation authorizing the collection of user fees, FDA has devoted its efforts to developing its implementation policies and procedures as well as enhancing its recruitment systems. FDA has begun implementing a number of management initiatives to accelerate the review process. These include: the practice of conducting concurrent reviews by both the primary and secondary reviewers; the use of pre-filing meetings and 45-day Filing/Planning meetings; the combination of statistical and medical reviews into one review; and the application of computer-assisted project management systems to manage the review process and maximize resources.

On July 22, 1993, the Agency published a guideline calling for better assessment of possible gender differences in response to new medications. The new guideline will help ensure that the safety and efficacy of drugs are adequately studied in the full range of patients who will receive therapy and encourages companies to include patients of both sexes in drug development as well as analyze the effectiveness and safety databases to look for significant differences in response between men and women. The elimination of the 1977 restriction of women of childbearing potential in early clinical trials reflects the Agency's view that institutional review boards, investigators, and patients should play a greater role in determining whether the participation of women in trials is appropriate and how best to ensure that there is no exposure of a fetus to potentially toxic agents.

6. Strengthening Postmarketing Surveillance Activities

FDA continues to monitor drugs after approval to detect those safety problems which only become evident in postmarketing conditions of use. The Spontaneous Reporting System currently contains over 1,000,000 adverse drug event reports (ADEs). Over 108,000 ADE reports (plus 15% follow-up reports) were received from drug manufacturers in 1993, according to their requirements under the adverse drug reactions reporting regulations (21 CFR 314.80 and 21 CFR 310.105). An additional 13,000 reports of ADEs were received directly from health professionals. Each report was automated and evaluated for evidence of unknown adverse events.

Sharing information on these reports internationally and learning of potential signals of toxicity in marketed drugs in other parts of the world is of great importance to FDA. Consequently, the Agency participates actively in the WHO's Collaborative Center for International Drug Monitoring. This group not only shares information among regulatory agencies around the world, but

fosters dialogue between regulators and the pharmaceutical industry to facilitate the safe marketing and use of drugs and other medical products. In addition, FDA has been an active participant in the Council for International Organizations of Medical Sciences (CIOMS) special working groups that have begun to improve international harmonization of regulations governing manufacturers' requirements of submission of adverse event information. An outgrowth of this has been the identification and acknowledgment of the need for globalization of the terminology used in describing ADE's. FDA has been a leader in launching an international collaborative endeavor toward this goal.

Within the U.S., the reporting of ADE's remains voluntary on the part of health professionals. In 1993, FDA launched MedWatch, a program designed to educate health professionals about the importance of their role in reporting adverse events. The program also succeeded in eliminating the need for multiple reporting forms for different types of products. Any adverse event for any type of medical product can now be reported on one form, the FDA-3500, or MedWatch form. CDER has been an extremely active participant in the MedWatch effort, not only in these areas but in the educational aspects of the programs as well, attempting to facilitate better and more frequent reporting of adverse events that can be classified as serious in nature.

As a result of MedWatch, FDA is anticipating receiving both an increased number and an increase in the quality of ADE reports. The system for the automation of ADE reports will consequently require upgrades in information management. The future focus will be on a system, including hardware, software and personnel, that will provide an enhanced level of integration, improved standardization, expanded functionality, and greater efficiency and accessibility. Plans and initial systems are also in place for electronic reporting by health professionals. Plans for electronic reporting by industry are under development. Internally at FDA, methodologies are being developed for expanded and integrated systems for the detection and follow-up of signals for unexpected and serious ADEs in order to provide more readily available health and risk information for the Agency, manufacturers and health professionals.

There were 29 monitored adverse events (MARs) in 1993, which are serious drug adverse event associations that fall outside the labeling for the drug. These often resulted in labeling changes and other actions, including in some cases, the issuance of letters to health professionals warning them of new adverse event profiles detected. Other signals resulted in FDA working with

pharmaceutical firms to alter their promotional campaigns and/or target their educational efforts to minimize the occurrence of ADE's. In at least one case, efforts such as these allowed a product that was removed from the market in another country to remain available on the market for prescription use in the U.S.

There were numerous postmarketing issues investigated during 1993. Once a signal of an unknown serious adverse drug event is detected, pharmacoepidemiologic methods are used to assess the strength and the importance of the association using available drug use data, Medicaid data and data available from several longitudinal patient-linked databases. In 1993, FDA published a request for applications seeking to expand its access to such databases in order to conduct studies designed to evaluate the use and safety of marketed products. Ongoing studies include the evaluation of hepatotoxicity associated with zidovudine, use of benzodiazepines and their relationship to the occurrence of hip fractures in elderly women, and the risk of ventricular arrhythmia reactions associated with non-sedating antihistamines.

Assurance of drug quality is another important part of FDA's postmarketing surveillance program. Reports of drug quality problems are reported to and investigated by FDA with consequent correction of manufacturing procedures by the pharmaceutical industry.

7. Over-the-Counter (OTC) Monograph Development

Through rulemaking procedures, the Agency continued to establish standards for therapeutic categories of OTC drugs by publishing final monographs or regulations in the FEDERAL REGISTER. To date, final rules have been published for 49 categories of OTC drugs.

In 1993, the following OTC documents were published in the FEDERAL REGISTER:

Final Rules

Status of Certain Additional OTC Drug Category II and III
 Active Ingredients Drug Products
 Smoking Deterrent Drug Products
 Warning Statements Required for OTC Drugs Containing
 Water-Soluble Gums as Active Ingredients
 Topical Antifungal Drug Products; Certain Labeling Claims
 Anorectal Drug Products (LYCD)
 Nailbiting and Thumbsucking Deterrent Drug Products
 Ingrown Toenail Relief Drug Products
 Topically Applied Hormone-Containing Drug Products
 Topical Antifungal Drug Products
 Digestive Aid Drug Products

Astringent (Skin Protectant) Drug Products
 Boil Treatment Drug Products
 Pediculicide Drug Products

Final Rule Amendments

Antacid Drug Products
 Bronchodilator Drug Products (MAOI Statement)
 Antitussive Drug Products (MAOI Statement)

Proposed Rules

Labeling of OTC Drug Products
 Sunscreen Drug Products
 Cosmetic Drug Products Containing Certain Hormone
 Ingredients
 Overindulgence in Food and Drink Drug Products
 Laxative Drug Products
 Labeling for OTC Oral Drug Products Containing Aspirin,
 Buffered Aspirin, or Aspirin in Combination with Antacid
 Labeling of Oral and Rectal OTC Drug Products Containing
 Aspirin and Nonaspirin Salicylates
 Drug Products Intended for Oral Ingestion that Contain
 Alcohol

Proposed Amendments of Final Monographs

Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products
 Antiemetic Drug Products
 Nighttime Sleep-aid Drug Products
 Antacid Drug Products

In 1994, the following FEDERAL REGISTER publications are
 projected:

Final Rules

Drug Products Intended for Oral Ingestion that Contain
 Alcohol
 Laxative (Package Size Limit) Drug Products
 Reye Syndrome (Nonaspirin Salicylate) Drug Products
 Anticaries Drug Products
 Nasal Decongestant Drug Products
 Leg Muscle Cramps Drug Products
 Antidiarrheal Drug Products
 Labeling for OTC Drug Products (Similar Words)

Final Rule Amendments

Antiemetic Drug Products
 Nighttime Sleep-aid Drug Products
 Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products
 Antihistamine (Doxylamine Succinate) Drug Products

Proposed Rules

Quinine for Malaria Drug Products
 Health Care Antiseptic Drug Products
 Vaginal Contraceptive Drug Products
 Oral Health Care (Oral Antiseptic) Drug Products
 Required Labeling for Benzoyl Peroxide

Proposed Amendments of Final Monographs

Wart Remover Drug Products
 Antacid (Sodium Bicarbonate) Drug Products

Advance Notice of Proposed Rulemaking

Vaginal Drug Products Withdrawal

8. Drug Enforcement Actions

In 1993, FDA took a number of human drug compliance actions to safeguard the public health, including seizures of defective products, injunctions and prosecutions. Over 500 Warning Letters were issued to the regulated industry for significant violations in need of correction. Difficulty in complying with the Agency's current good manufacturing regulations continued to be a stumbling block, even for major U.S. manufacturers. In August 1993, under a consent decree of permanent injunction in the U.S., District Court for the District of New Jersey, the Warner-Lambert Company agreed to correct deficiencies in manufacturing practices uncovered by numerous FDA inspections in six different plants. FDA took action when the firm did not deal with these problems which included failure to notify the Agency of batches of drugs that failed product stability tests, the use of unapproved production processes, and inadequately trained personnel. The company recalled many of their drug products from the market as a result of these findings.

The Agency also continued vigorous prosecution of criminal violations which frequently result from cooperative investigations with other federal and state agencies. In one case, FDA personnel worked with the U.S. Customs Service; U.S. Internal Revenue Service; and the states of California and Florida to seize more than 100 potentially dangerous unapproved and seriously mislabeled prescription drugs.

In 1993, prior criminal cases were brought to a close with fines levied on several drug companies and sentencing of certain company officials found guilty because of fraud in the manufacturing of generic drugs. In related actions, FDA debarred thirty-six individuals under the Generic Drug Enforcement Act of 1992 from submitting or assisting in the submission to FDA of Abbreviated New Drug Applications for generic drugs because of their felony convictions of such crimes as giving unlawful gratuities to FDA officials, making and submitting false statements to FDA, obstruction of justice, and engaging in interstate travel in aid of racketeering.

9. Prescription Drug Advertising and Labeling

In 1993, FDA continued to regulate prescription drug advertising and labeling by monitoring all prescription drug promotions; enforcing the existing Agency policies that regulate those promotions; and, developing new policies to support the surveillance and enforcement efforts.

Surveillance and Enforcement. The Agency furthered its effort to regulate drug advertising by taking enforcement actions and by issuing guidance letters to industry. On July 29, 1993, the FDA entered into a consent decree against Kabi Pharmacia, Incorporated, and its president concerning Kabi's advertising and promotional activities and materials for Dipentum, indicated for the maintenance of remission of ulcerative colitis in adult patients who are intolerant of sulfasalazine. Additionally, the Agency issued four Warning Letters in 1993 to companies in violation of the advertising and labeling provisions of the Food, Drug and Cosmetic Act. Finally, FDA sent four letters to the pharmaceutical industry to provide guidance on and clarify current advertising and labeling issues such as telephone advertisements, direct-to-consumer advertisements, and policy on solicited and unsolicited requests for information.

Policy Development. In 1993, the Agency continued to develop policies to support its regulatory efforts. FDA reviewed and prepared responses to the comments concerning the policy statement on industry-supported scientific and educational activities. FDA continued to refine its wording policies concerning prescription drug promotion through audiovisual media and direct-to consumer advertising. The Agency also furthered review of its plans for regulating economic, quality of life, and comparative claims made in prescription drug promotion.

Additional Measures. FDA has also continued its research, education and outreach activities. Work continued on a number of research projects related to communications about prescription drugs to important target audiences, including analysis and write-up from an updated national survey of information received by patients about the drugs prescribed for them and conduct of a survey of physicians' perceptions of prescription drug labeling and the summary of prescribing information included in prescription drug advertising.

ORPHAN PRODUCTS DEVELOPMENT

STATUS OF PROGRAM

FDA continues to carry out a program encouraging the development of drugs, biologicals, medical devices and medical foods for rare diseases and conditions. The agency met with ten potential sponsors of orphan drugs in 1993. The sponsors were given information on the development of these drugs and guidance on applying for "designation" as an orphan drug under the Federal Food, Drug and Cosmetic Act. It is anticipated that such help will be continued at this level in 1994 and 1995.

During 1993, FDA completed scientific reviews on 67 new sponsor requests for designation of drugs as orphan drugs in addition to 36 applications submitted prior to 1993 and amended in response to FDA letters. As part of the review, the sponsor is required to submit data adequately demonstrating the use of the drug for diseases or conditions affecting less than 200,000 people in the U.S. Based on these reviews, 60 drugs received designation as orphan drugs during the year (as of December 15, 1993). A total of 617 designations have been made since the enactment of the Orphan Drug Act. It is estimated that the FDA will review 70 sponsor requests for orphan designation in 1994.

Under the FDA Orphan Products Grants Program \$2,584,154 was awarded for 20 new and competing continuation studies in 1993. These studies were designed to provide information on human safety and effectiveness of drug products for diseases and conditions like: Infant Botulism, Wilson's disease, Trigeminal Neuralgia, Macular Holes, Familial Amyloidosis, Autism, Pediatric Myoclonus, and 5-Oxoprolinuria. Additionally, \$6,560,846 was spent during the year for continuation studies begun in prior years.

These designated orphan drugs were approved for marketing in 1993:

Antihemophilic factor (recombinant) Kogenate - Prophylaxis and treatment of bleeding in individuals with hemophilia A or for prophylaxis when surgery is required in individuals with hemophilia A.

Cladribine (Leustatin Injection) - Treatment of hairy cell leukemia.

Dornase alpha (Pulmozyme) - To reduce mucous viscosity and enable the clearance of airway secretions in patients with cystic fibrosis.

Felbamate (Felbatol) - Treatment of Lennox-Gastaut syndrome.

Interferon beta, recombinant, human (Betaseron) - Treatment of multiple sclerosis.

Leuprolide acetate (Lupron Injection) - Treatment of central precocious puberty.

Levomethadyl Acetate hydrochloride (Orlaam) - Treatment of heroin addicts suitable for maintenance on opiate agonists.

Lodoxamide tromethamine (Alomide Ophthalmic Solution) - Treatment of vernal keratoconjunctivitis.

Megestrol acetate (Megace) - Treatment of patients with anorexia, cachexia, or significant weight loss ($\geq 10\%$ of baseline body weight) and confirmed diagnosis of acquired immunodeficiency syndrome.

Somatropin for Injection (Nutropin) - Treatment of growth retardation associated with chronic renal failure.

Trimetrexate Glucuronate (Neutrexin) - Treatment of pneumocystis carinii pneumonia in AIDS patients.

BIOLOGICS

STATUS OF PROGRAM

The Biologics program is responsible for assuring the safety, effectiveness, purity, and potency of biological products and for assuring the safety of the nation's supply of blood and blood products.

Current Activities. To accomplish these responsibilities, FDA:

1. Administers an Acquired Immune Deficiency Syndrome (AIDS) program, including research on AIDS diagnostic tests, therapeutic products, and vaccines and maintains liaison with the PHS Office of AIDS Coordination.
2. Evaluates the safety and effectiveness of biological products before marketing and monitors the preclinical and clinical testing of new biological products.
3. Issues licenses to manufacturing establishments including plasmapheresis centers, blood banks, vaccine producers, and others; and issues licenses for biological products.
4. Maintains the quality of marketed products through surveillance and compliance actions: conducts inspections of licensed and unlicensed biological manufacturing establishments to assure compliance with established regulations and good manufacturing practices; removes from the marketplace those products that do not meet established standards.
5. Conducts potency and safety tests of licensed biological products before they are released for marketing.
6. Maintains up-to-date knowledge of biotechnological techniques and methodologies to foster the development of new products and provide a sound scientific basis for their regulation.
7. Sponsors and conducts research to establish product standards and develop analytical methodologies and improved test methods.
8. Registers regulated manufacturing and blood banking establishments; maintains listings of all biological products commercially marketed in the U.S.
9. Develops regulations, including Current Good Manufacturing Practices (CGMP) regulations and compliance programs and provides support and guidance to the Field on legal actions and case development.

10. Presents to Advisory Committees available data relating to the safety, effectiveness, and appropriate use of specific biological products.

Selected Examples of Recent Progress:

1. Acquired Immune Deficiency Syndrome (AIDS)

As the AIDS epidemic enters its second decade, and sources predict the global number of documented cases of AIDS will increase tenfold by the year 2000, FDA continues intensified efforts to combat AIDS through biological products intended for the diagnosis, prevention, and treatment of AIDS and AIDS-related diseases.

FDA received 53 AIDS INDs during FY 1993, an increase of 15 over receipts during FY 1992. A total of 13 HIV vaccines are now being evaluated in clinical trials--10 as preventatives in uninfected volunteers and 10 as therapeutics in people infected with HIV disease. Two recombinant vaccines are currently in Phase II trials in high risk uninfected volunteers. Trials have also been initiated in neonates born to HIV-infected mothers. These infants are considered to be at high risk for immediate transmission from mother to infant.

FDA's applied research activities have played a significant role in the development of vaccines, therapeutic agents, and test kits for possible use in AIDS and AIDS-related conditions by defining parameters that must be met regardless of product or sponsor. FDA continues to enlarge the scope of its AIDS-related activities as new data on HIV, AIDS, and AIDS-related diseases accumulate and as clinical trials of new therapies, vaccines, and diagnostic tests expand.

Protection of the National Blood Supply. FDA continued to strengthen its efforts to protect the nation's blood supply and to minimize any risk to patients of acquiring human immunodeficiency virus (HIV), hepatitis and other blood borne diseases. Annual inspections of all blood centers focus on procedures used by the blood and plasma industry in donor screening, testing for viral markers for diseases and syndromes such as AIDS, and procedures for quarantine and destruction of unsuitable blood products. Each of the over 12 million units of blood collected annually presents potential safety concerns, and its processing into separate blood products such as red blood cells, plasma and platelets results in a number of further products that are also subject to concerns, such as HIV. Complexities resulting from the use of additional laboratory screening tests, as well as institution of more computer-controlled deferral, quality control, and distribution systems by

blood and plasma facilities, require more time-intensive inspections and increased follow-up and oversight by FDA inspectors. During 1993, approximately 3,000 inspections of licensed facilities were conducted.

FDA has intensified its oversight of blood establishments and has documented the release of unsuitable blood and blood components in situations when deficiencies have occurred. In response to FDA recommendations regarding the responsibilities of blood establishments, the industry submitted almost 9,000 reports of errors or accidents. These reports led to 8 license suspensions, 10 license revocations, and 463 product recalls.

FDA distributed several guidance documents and controls to the blood industry to help them address in a standardized fashion several difficult areas of blood and plasma collection and processing. The most important guideline was the "Guideline for Quality Assurance in Blood Establishments" which outlines FDA's expectations of the base line levels of quality assurance and testing which each blood establishment must meet. FDA published a proposed rule entitled "Current Good Manufacturing practices for Blood and Components; Notification of Consignees Receiving Blood and Components at Increased Risk for Transmitting HIV Infection." This policy addresses retrieval of potentially contaminated products, and notification of recipients when a previous donor is later found to be HIV infected. Other important documents include recommendations about the licensing and production of blood products that are gamma irradiated to prevent graft versus host disease in severely immunosuppressed patients, an update of the list of medicines for which a blood donor should be deferred (Proscar, Accutane, Tegison and pituitary derived Growth Hormone), and revised "Recommendations for Testing Whole Blood, Blood Components, Source Plasma, and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (anti-HCV)" to go with the approval of the second generation HCV-RIBA assay.

Development and Evaluation of Blood Tests: The development of improved and more effective blood tests is a priority issue at FDA. Approximately 78 INDs for in vitro diagnostics have been received. The most significant new test approved in 1993 was a more specific test for Hepatitis C virus antibodies. The second generation HCV-RIBA offers a further, more specific test for identifying those persons who are infected with the Hepatitis C virus. FDA also released the first control panel for lot release of test kits to detect antibodies to HIV-2 and an improved panel for lot release testing to detect antibodies to Human T-Lymphotropic Virus Type-I (HTLV-I).

2. Biotechnology

Biotechnology continues to play an important role in the discovery and development of new biological products for the diagnosis, treatment, or prevention of serious and life-threatening diseases. Biotechnology techniques are now used routinely to produce novel and highly complex biological, therapeutic and diagnostic agents and vaccines. Biotechnology methods have led to the development of products that were previously not feasible; that may be less toxic because they are more specific (e.g., "programmed" to attack only tumor cells leaving healthy cells alone); and that can be economically manufactured in large quantities. Many of these products are intended for use against diseases for which no known therapy exists. One of the fastest growing areas is in the area of gene therapy. Advances in virology, cell biology and biotechnology have joined together to produce novel approaches to three main areas of life-threatening diseases, cancer, AIDS, and genetic diseases such as cystic fibrosis.

Over the past years, the number of investigational new drug (INDs) submissions has increased dramatically from fewer than 5 INDs in FY 1980 to several hundred in FY 1993. An important subset of this growth has been in the area of gene therapy which has grown from three submissions in 1991 to more than 20 in FY 1993. Importantly, adjunct procedures used in gene therapy protocols such as stem cell isolation are also rapidly increasing, leading to a secondary rise in device and biological submissions related to this area. In addition, an entirely new class of recombinant cytokines, the neurotrophic growth factors, hold great potential for the treatment of neurodegenerative diseases such as, Alzheimer's, Amyotrophic Lateral Sclerosis (ALS), and Parkinson's disease.

A major approval in 1993 was the first product licensed for the treatment of multiple sclerosis. Interferon beta-1b, was the first biotechnology product to be licensed under FDA's accelerated approval regulations which expedite the approval of therapies that provide a meaningful benefit for patients with serious illnesses. Nearly 30 percent of multiple sclerosis patients suffer from a relapsing-remitting form in which symptoms disappear totally or partially after a flare-up and are followed by a period of stability that can last for months or years. Although not a cure, in clinical trials, administration of interferon beta-1b decreased the frequency of flare-ups of multiple sclerosis and kept more patients free of flare-ups over a two year treatment period.

The second approval under the expedited review procedures was Dornase alpha, or DNase which is a novel treatment for cystic fibrosis. DNase was licensed nine months after submission. The enzymatic action of DNase cuts the viscous strands of DNA that

are found in excess in the lungs of cystic fibrosis patients. In double blinded placebo-controlled trials, DNase led to both decreases in infection rate and increases in patient well-being. DNase, a product of recombinant DNA technology, is not a cure but is the first treatment that specifically improves lung function in cystic fibrosis patients.

Additional indications for muromonab-CD3 and epoetin alpha were also approved in 1993. Muromonab-CD3, a monoclonal product initially licensed in 1986 for the treatment of acute kidney transplant rejection, was additionally approved for treatment of acute rejection in heart and liver transplant patients who are resistant to standard steroid therapy. Epoetin alpha, initially licensed for anemia associated with chronic renal failure and AZT-induced anemia in HIV infected patients was approved to expand its use for treatment of anemia associated with cancer patients in chemotherapy.

The second recombinant Factor VIII used to correct or prevent bleeding episodes in patients with hemophilia A was approved. Hemophilia A is a rare hereditary disease that affects (primarily) males. Previous methods used to manufacture Factor VIII (plasma-derived) resulted in the transmission of hepatitis and HIV, while the recombinant DNA technology eliminates this possibility. Both factor VIII products, the first one approved in 1992, represent a milestone in biotechnology development of large and complex human proteins.

Specific ongoing basic research by FDA scientists include studies relevant to the development of gene therapy protocols such as how genes are turned on and off and how genes may be targeted to specific sites within the genome; studies on the phenomenon of programmed cell death (apoptosis) which is proposed to treat cancer by causing apoptosis in cancerous cells; research to determine the genetic basis of malignancy, specifically chronic lymphocytic leukemia; studies on the effects of interleukin-4 on human solid tumors; research on new methods of vaccination using direct injection of genes into animals; studies on the human retroposon in terms of how it moves about the human genome, and new tumor antigens as potential targets for immunotherapy, particularly in the area of neuroendocrine neoplasia; studies addressing basic rules that govern monoclonal antibody diversity and mutation, and how cytokines work and their role in host defense and disease processes.

To expedite the transfer of the advances of biotechnology from the laboratory to the marketplace, FDA has taken the following initiative: (1) created a new Division which has responsibility for cellular and gene therapies. (2) presented interim guidance at many meetings and workshops, (3) held a Viral Vaccine Advisory Committee meeting on the safety of viral vectors for gene therapy, and (4) sponsored a Workshop on Clinical Trial Issues of

Topical Wound Healing Biologicals to address this different class of recombinant cytokines which show great promise. Examples include products for various wounds such as diabetic ulcers, thermal burns, and ophthalmologic indications.

A revised draft of the 1987 document "Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals" was issued in 1993. The revision provides current guidance on analytical approaches with a strong focus on the identification of possible adventitious infectious agents from cell lines which might contaminate the final product. Additional guidance included a Federal Register notice on the "Application of Current Statutory Authorities to Human Somatic Cell Therapy", and journal articles on the "FDA Regulations of Somatic-Cell Therapy and Gene Therapy", and "The Safety of Retroviral Vectors."

3. Vaccines

Two of the most important public health initiatives for vaccines are the development of new combination vaccines to promote the objectives of the Children's Vaccine Initiative (CVI) and the development of efficacy and safety data to license acellular pertussis vaccines for infants (since whole-cell pertussis is the most reactogenic and controversial of the pediatric vaccines).

Two combination vaccines were licensed during the past year. The first combination vaccine (tradename Tetramune), licensed in March 1993, is a combination of an Haemophilus influenza type b conjugate and DTP. Tetramune was licensed for use at all ages in which both DTP and Haemophilus vaccines are indicated, i.e., infants and pre-school children.

Also in March 1993, an Haemophilus influenza type b conjugate was licensed for infant use. This was the first Haemophilus conjugate vaccine to be licensed using serum antibody levels as a surrogate marker for efficacy. This was followed in November 1993 by the licensure of PRP-T reconstituted with DTP as the second combination vaccine for the prevention of these four diseases (Haemophilus b disease, pertussis, diphtheria, and tetanus).

The National Institute for Anti-Infective Diseases (NIAID)-sponsored acellular pertussis vaccine trials in infants in Sweden and Italy progressed significantly during 1993. Both studies are on track in terms of enrollment, immunization, cases of pertussis, and other trial design criteria. The FDA is participating in these studies through vaccine characterization and monitoring serum antibody response.

FDA sponsored a workshop on issues and perspectives related to combined vaccines and simultaneous administration of vaccines. The three-day workshop was attended by over 700 scientists,

academic clinicians, and representatives from regulated industry. The proceedings of the meeting will be published in the Annals of the New York Academy of Science.

Several clinical trials for important vaccines were begun during 1993. These include a trial for a Lyme disease vaccine and a phase II trial for two HIV vaccines sponsored by the NIAID. The NIAID also initiated HIV vaccine studies in infants born to HIV-infected mothers.

CBER recommended the composition of the trivalent inactivated influenza virus vaccine for the 1993-4 flu season. The flu vaccine includes a component for each of the three types of influenza virus affecting people around the world. Two of the strains, A/Texas/36/91 and B/Panama/45/90, were contained in last season's vaccine. A new strain, A/Beijing/32/92, was the third component and was selected because of its marked antigenic difference from previous, related influenza strains and its pattern of outbreak in various populations.

FDA scientists are continuing to study methods for the detection of adventitious agents in biological products. As an example, the methods of molecular biology are being used to detect the presence of replication competent viruses in cell and gene therapy products. These studies were presented at the October meeting of the Vaccines Advisory Committee. This year, the agency made available revised guidance concerning cell substrate issues.

New assays were developed for the standardization of allergenic extracts. Validation studies were completed on 10 products (8 grass pollens and two mite extracts). With the implementation of these assays, the expense and the personnel time for industry and FDA will be reduced. Studies are now proceeding with other allergens, including ragweed and cockroach.

A workshop was conducted for manufacturers and allergenic product testing laboratories to familiarize and train regulatory and scientific staff in the use of a newly developed ELISA (enzyme-linked immunosorbent assay) competition assay to replace the currently used RAST (radioallergosorbent test) inhibition assay for potency of allergenic products. Twenty one scientists and regulators from industry participated in this week-long training session.

4. Management Improvements and ADP Enhancements.

FDA continues to make significant advances in its efforts to shorten review time of certain new drugs and biological products for serious or life-threatening illnesses. The Prescription Drug

User Fee (PDUF) Act of 1992 has streamlined drug and biologic review processes and increased the use of information technology to help speed reviews, as well as, shorten review times of product and establishment license applications significantly.

A refusal-to-file policy was issued by CBER which enables the review divisions to return to application sponsors incomplete or inadequate product license applications (PLAs). The refusal-to-file is an early signal to the sponsor that the application has major deficiencies that would, with high probability, result in a non-approvable action or requests for substantial amounts of additional data and/or analyses if a full review were conducted, or would introduce significant impediments to a prompt review. The signal is transmitted to the sponsor very early, so that changes can be made to the application promptly. Sponsors may appeal a refusal-to-file decision.

Additionally, CBER established a project management system to track and report user fee applications and supplements. The managed review process incorporates the team approach to review and employs concepts of project management. The system establishes specific timeframes within which intermediate goals or milestones should be accomplished in the review of PLAs, establishment license applications (ELAs) and supplements. A computerized database has been established that calculates milestone "due dates" for each application, thus ensuring completion of reviews and final actions (e.g., approval, approvable, not approvable, denial) on applications within the performance goal timeframes mandated under the PDUF, as well as some non-user fee applications.

A User Fee Recruitment Tracking Task Force (UFRTTF) was established to assess the needs of the additional FTEs under the user fee recruitment initiative and to assure that they were brought on board in an expedited manner with the resources required to be highly productive quickly. UFRTTF created a database to provide critical administrative data to responsible officials in areas of space, facilities, specialized equipment, training, telecommunications and ADP equipment to facilitate high productivity in a short timeframe.

Enhanced application review and inspection training was conducted during FY93. A series of training modules for reviewers and inspectors began in response to the Prescription Drug User Fee Act to ensure consistency in application review and improve establishment inspections. The training modules focused on the Agency's mission to provide complete review of the safety and efficacy of all biological product applications, and to assure compliance with established regulations and current good manufacturing practices (CGMPs). The training modules have

significantly increased the efficiency and productivity of reviewers and inspectors to expedite the application review and inspection processes; as well as decrease the backlogs of product and establishment applications and supplements.

A "Report Reduction Working Group" was also established in CBER to address a means to reduce its review workload as well as concerns of regulated industry related to manufacturing reporting burden and delay in implementation of important manufacturing changes. The group's efforts have focused on the Center's interpretation and implementation of 21 CFR 601.21 - Changes To Be Reported, as the primary instrument affecting reporting burden.

Recent information management initiatives have significantly improved the efficiency and productivity of CBER staff and enhanced the Center's ability to implement the User Fee legislation.

Major enhancements to the Oracle-based Biologics Decision Support System (BDSS) recently have included the implementation of User Fee Tracking, including the Office of Financial Management (OFM) interface, and the inclusion of Orphan Drugs.

Implementation and User Training for a major upgrade to the Biologics IND Management System (BIMS) is currently underway. This will allow interoperability with BDSS.

FDA has implemented several initiatives in the Biologics program for improved information management. The agency has continued to upgrade older VAX processors which were severely overloaded with new technology. The improvement in user access supports the Biological Decision Support System and implementation of the All-In-One messaging application. A "Points To consider" document providing guidance to manufacturers on the submission of Computer-Aided Program License Application submission was approved only 12 months after submission. A program was initiated that facilitates the review of investigational products through allowing the sharing of critical information among the scientific and clinical reviewers. This program will also be used to provide trend data and evaluate resources, as well as automate the tracking of submissions.

ANIMAL DRUGS AND FEEDS

STATUS OF PROGRAM

Current Activities. The Animal Drugs and Feeds program is designed to ensure that veterinary drugs are safe and effective, that animal feeds are not adulterated, and that neither animal drugs nor feeds constitute a human health hazard because of residues which remain in meat, milk or eggs. To carry out this mission, FDA:

1. Evaluates Notices of Claimed Investigational Exemption for Investigational New Animal Drugs (INADs) and New Animal Drug Applications (NADAs) to ensure that drugs will be safe and effective for animals and that no harmful drug residues will occur in foods derived from animals.
2. Monitors the veterinary drug production industry by reviewing Drug Experience Reports (DERS) which are required for approved animal drugs.
3. Monitors feed and feed ingredients, reviews and approves medicated feed applications, inspects feed mills, and conducts industry information programs to ensure that animal feeds are not adulterated.
4. Works closely with the U.S. Department of Agriculture (USDA) to determine and reduce the incidence of animal drug residues, pesticides and/or industrial chemicals in edible animal tissue.
5. Develops analytical methodologies to be used by FDA for supporting regulatory activities, and by USDA for surveillance of drug residues. Assists the states by ensuring that adequate methods are available for measuring drugs in animal feeds.
6. Conducts regulatory research related to tissue residues and toxic compounds in animal feeds.
7. Prepares for new technologies and emerging industries such as aquaculture, biotechnology and the impact of automation.

Selected Examples of Recent Progress:

1. Review of New Product Applications

During 1993, the office of New Animal Drug Evaluation acted on 5,062 submissions for new animal drug applications (NADAs) and investigational new animal drug applications (INADAs). Of these 151 were on original new drug applications, and 681 were on supplements to previously submitted applications. Approximately 90

percent of the 5,062 decisions were made within the statutory limit of 180 days for NADAs and the internally established time frame of 90 days for INADAs.

In 1993, the Agency finalized 38 significant approval actions. These approvals included new chemical entities, new dosage forms of approved drugs, and new combinations of approved drugs.

A sampling of the FY 1993 approvals follows:

<u>Drug</u>	<u>Species</u>	<u>Type of Action</u>
Diazepam	Dogs	Original New Chemical Entity
Yohimbine HCL	Deer/Elk	Original, Additional Species
Praziquantel	Dogs/Cats	Indications of Use, New Claim
Pirlimycin	Cattle	Original, New Chemical Entity
Formalin	Shrimp	New Species

2. Monitoring Illegal Use of Animal Drugs

The Agency continues its efforts to ensure that harmful drug residues do not remain in foods. FDA approved veterinary drugs account for 90 percent of all marketed drugs used in food animals. Residues of the remaining products have no known risk to humans.

FDA believes a mechanism, similar to that used for human drugs, is needed to control the illegal distribution of veterinary prescription drugs among animal producers. The key to effectiveness of such a system is the establishment of a full partnership with the states, including the state licensing of wholesale distributors and pharmacists. With this in mind, the Association of Food and Drug Officials, in conjunction with other state regulatory officials and with FDA's assistance, approved a model veterinary drug code which should provide a basis for uniform state laws and regulations for veterinary drug distribution.

3. Meat Residue Monitoring

The meat residue monitoring program is the foundation of the government's efforts to ensure that food derived from animals contains no harmful drug residues. FDA and USDA work closely with each other, and in cooperation with state agencies in carrying out effective monitoring and efficient analytical methods to detect

residues of toxicological concern. Twenty-six states have joined with FDA via a variety of cooperative agreements to conduct follow-up investigations of USDA reported violations: New Jersey, Pennsylvania, West Virginia, Virginia, Maryland, Delaware, Kentucky, South Carolina, North Carolina, Georgia, Florida, Tennessee, Alabama, Louisiana, Mississippi, Michigan, Wisconsin, North Dakota, South Dakota, Texas, Iowa, Nebraska, Kansas, California, Vermont, and Washington. Twelve of the states listed above are under contract to perform follow-up investigations on first time violators. These states account for about 75% of the food produced domestically from food producing animals.

FDA has also joined with USDA to employ a balanced measure of voluntary compliance, education, and regulatory enforcement for programs to reduce sulfamethazine residues in swine. With cooperation of the leadership of the swine producer organizations and agribusiness these programs have been highly successful in reducing the violation rate from 13% to less than 1%. Extensive efforts have also been undertaken with the dairy industry to educate farmers on proper drug use and to stop illegal use of sulfamethazine in lactating dairy cows.

4. Implementation of the Generic Animal Drug and Patent Term Restoration Act

In accordance with the Generic Animal Drug and Patent Term Restoration Act, FDA performs monthly updates on the listing of all animal drugs approved for safety and effectiveness which was originally published in 1989. This list includes information on patent exclusivity, producer withdrawals, and suitability petitions.

The Generic Animal Drug Committee and the Bioequivalency Committee continue their work related to the implementation of the Act. The Generic Animal Drug Committee is responsible for developing regulations and guidelines governing implementation while the Bioequivalency Committee is responsible for revising bioequivalency guidelines to comply with the new law.

FDA continues to review bioequivalency study protocols for Abbreviated New Animal Drug Applications (ANADAs). In FY 1993 seven ANADAs were approved.

5. National Drug Residue Milk Monitoring Program

Another of FDA's primary responsibilities is the regulation of milk which is shipped in interstate commerce. FDA's milk safety program relies heavily on participation by state regulatory agencies. This participation is described in a 1977 Memorandum of Understanding (MOU) between the National Conference on Interstate Milk Shipments (NCIMS) and the FDA. The NCIMS program provides strong assurance

of a clean and safe national milk supply. The FDA, with the support of the NCIMS has initiated the National Drug Residue Milk Monitoring Program (NDRMMP). The NDRMMP is designed to assist and supplement the longstanding NCIMS program.

The NDRMMP provides information on animal drug residues that might be present in milk and the extent that farmers, distributors, and veterinarians comply with Federal regulations concerning drugs and dairy cattle. The NDRMMP encourages the use, development and validation of new analytical methods in state and other laboratories and particularly in laboratories where the assay of raw milk is routine. The FDA has shared new analytical methods with states. An important benefit of NDRMMP is the transfer of analytical technology from FDA to state and industry laboratories and then the transfer of improvements and refinements among all participating laboratories.

The results from the NDRMMP are used in the design of future education and compliance efforts for use by Federal, state and local authorities. This initiative will enhance the NCIMS residue testing program and provide information on which to focus regulatory priorities.

MEDICAL DEVICES AND RADIOLOGICAL PRODUCTS**STATUS OF PROGRAM**

The primary goals of FDA's Medical Devices and Radiological Products program are: 1) to ensure the safety and effectiveness of medical devices, and 2) to eliminate unnecessary exposure to radiation from medical, industrial, and consumer products while maximizing the benefits from necessary exposure.

Current Activities. To accomplish these goals, FDA conducts the following activities:

1. Classifies medical devices into the appropriate regulatory category (class I--general controls; class II--special controls; class III--premarket approval).
2. Reviews Premarket Approval Applications (PMAs) to ensure the data submitted by the manufacturer demonstrate the device is safe and effective.
3. Reviews Premarket Notifications [510(k)s] to ensure the data submitted by the manufacturer demonstrate the device is substantially equivalent to an eligible product already on the market.
4. Reviews Investigational Device Exemption applications (IDEs) to ensure proposed investigational studies will be well-controlled and will safeguard the rights and safety of human subjects.
5. Conducts postmarket surveillance to ensure the continued safety and effectiveness of marketed devices. Postmarket surveillance includes the mandatory manufacturer, distributor, and device user facility problem reporting programs and the voluntary problem reporting program, inspections of manufacturing facilities, postmarket surveillance studies, device registries, and other mechanisms.
6. Promulgates and enforces quality standards under the Mammography Quality Standards Act of 1992. These standards govern every significant aspect of mammography, including equipment, personnel, and quality assurance programs, and provide for accreditation, inspection, and certification of all mammography facilities.
7. Conducts research to provide a sound foundation for effective regulation by increasing FDA's understanding of the principles at work in, and the risks involved with complex devices.

8. Conducts educational activities to help consumers and health professionals use medical devices properly, thereby maximizing the benefits from devices while minimizing or eliminating inherent risks.
9. Provides technical, nonfinancial assistance to small medical device manufacturers. This assistance helps manufacturers comply with FDA regulatory requirements and contributes to improved safety and effectiveness of marketed devices.
10. When necessary to obtain full compliance with regulatory requirements or to protect the public health, conducts enforcement actions, such as mandatory recalls, PMA suspensions, seizures, injunctions, prosecutions, or the imposition of civil penalties.

Selected Examples of Recent Progress:

1. Product Review

During FY 93, FDA received 40 Premarket Approval Applications (PMAs), 665 PMA Amendments, 395 PMA Supplements, 6,288 Premarket Notifications [510(k)s], 241 Investigational Device Exemption applications (IDEs), 320 IDE amendments, and 3,668 IDE Supplements - a total of 11,617 major product review submissions.

FDA review times increased for both PMA and 510(k) submissions during FY 93. Average FDA review days for PMA approvals rose from 146 in FY 92 to 328 in FY 93. The rate of increase is misleading, however, since the majority of the PMA approvals issued in FY 92 involved an abbreviated review of licensing agreements rather than a full-blown review of safety and effectiveness data, resulting in much lower than average FDA review days in FY 92. Average FDA review days for 510(k)s rose from 102 in FY 92 to 162 in FY 93. This upward trend in 510(k) review times can be attributed to various factors including: FDA's first in-first out (FIFO) policy which, when operating in a time of increasing backlog, leads to longer waiting times before the application is even looked at; additional exemptions of class I devices (easy to review) from 510(k) review; enhanced documentation of decisions; and larger and more complex submissions. The backlog of 510(k)s has grown continuously over the last three years. Even though FDA completed 200 more 510(k)s in FY 93 than in FY 92, FY 93 receipts were 1,200 more than the number completed and only 200 fewer than FY 92 receipts. Thus, the most recently received applications have to wait longer for the review process to begin. This waiting time is included in the average FDA review time. The average FDA review time will begin to decrease once the backlog of pending applications is substantially reduced. For IDE submissions, the average FDA review time decreased during the year, dropping from 30 days in FY 92 to 28 days in FY 93.

In FY 93, FDA developed 43 new guidance documents for use by industry and FDA reviewers. These documents are designed to promote uniformity and to improve the efficiency, quality, and administration of FDA review programs. Several of the documents provided specific guidance for certain types of 510(k) and PMA submissions, clinical investigations, and laboratory test assessments.

2. Significant Medical Device Approvals/Clearances

During FY 93, FDA cleared for marketing several devices that represent significant advances in medical technology:

- On November 20, 1992, the Ventricular Assist Device was the first such device to receive FDA approval. It is intended for short term use in patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, allowing the heart to recover adequate mechanical function.
- On March 2, 1993, the FDA cleared the Accumeter Cholesterol Self-Test, the first in-vitro diagnostic device for home use to estimate a person's level of cholesterol. This simple test for cholesterol uses a single drop of blood from a fingerstick and takes about 15 minutes to perform. The firm's studies showed the test to be as accurate as cholesterol tests used by doctors and medical laboratories. The user will be able to determine if he or she has an increased cholesterol level and should see the doctor before a serious problem develops.
- On May 7, 1993, the Reality female condom was approved for marketing. The device, also known as a vaginal pouch, is the first condom-type barrier contraceptive for women. It offers some protection against sexually transmitted diseases (STDs).
- On May 28, 1993, the Gianturco-Roubin Flex-Stent was approved. This is the first coronary stent approved by FDA and is indicated for chronic placement in a coronary artery to obtain vessel patency in the treatment of acute or threatened closure associated with an interventional procedure.
- On August 26, 1993, ENDOTAK Transvenous Leads were the first transvenously delivered defibrillator leads to receive FDA approval. The use of these leads eliminates the need to perform a thoracotomy on patients receiving defibrillators, which lessen operative risks to the patients and reduces the post-operative recovery period.

3. Acquired Immune Deficiency Syndrome - AIDS

During FY 93, FDA approved the first female condom which offers women some protection against HIV infection. The data provided on the application was derived from a test method for virus

transmission that had been developed in FDA labs. This test method was developed to provide a method that would produce consistent results in the testing of both latex and natural condoms. In addition, FDA headquarters scientists worked with FDA Atlanta District Office scientists to establish a field capability for performing more widespread testing of the virus transmission properties of condoms and gloves.

FDA continued to investigate the implications of the activation of the HIV virus by ultraviolet (UV) radiation. FDA scientists initiated this study to determine if UV radiation emitted by devices regulated by FDA, such as photopheresis equipment and suntan beds, posed a hazard to HIV-infected individuals. In addition, the effect of treatment with psoralin drugs and UVA radiation on a variety of AIDS-related conditions was evaluated. During FY 93, FDA scientists worked with physicians on a pilot study with HIV-positive patients to examine whether HIV levels increased while patients were undergoing UV therapy. Initial results on a small group of patients showed no increase in HIV levels.

4. Safe Medical Devices Act of 1990 (SMDA)

Under the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992, Congress granted FDA additional authorities to increase early knowledge of serious device problems, to remove defective devices from the market more quickly, and to provide greater assurance of the safety and effectiveness of new medical devices. The laws also give FDA more options for regulatory action, streamline cumbersome procedures, and codify current Agency policies.

During 1993, FDA continued to implement numerous provisions of SMDA. Where appropriate, FDA used its new statutory authorities to assess civil penalties, to require manufacturers to conduct postmarket surveillance studies, and to require manufacturers, distributors, and hospitals to establish effective tracking systems for certain medical devices. In FY 93, FDA acted on 10 civil penalties cases and issued decisions on 65 required and 8 discretionary postmarket surveillance studies. FDA issued guidance to the field to assist in the timely development of mandatory recall and notification actions for hazardous products. FDA continued to receive and analyze adverse experience reports received under the mandatory reporting requirements for device user facilities and device distributors. In 1993, FDA reviewed approximately 2,300 device user facility and 950 device distributor reports.

Since enactment of the law, FDA spent considerable effort developing and publishing SMDA-related Federal Register documents.

In 1993, FDA published in the Federal Register two notices, two proposed rules, and two final rules relating to various SMDA provisions.

5. Postmarket Surveillance

Postmarket surveillance enhances consumer protection from risks associated with device use, particularly those which are neither apparent or foreseen during the premarket notification and premarket review processes. FDA conducts a variety of postmarket surveillance efforts. FDA collects, processes, and evaluates data received under the mandatory Medical Device Reporting regulation, which now includes the new SMDA user facility and distributor reporting requirements, the voluntary Problem Reporting Program (now included as part of MEDWatch, FDA's new consolidated adverse event reporting system), the Pacemaker Registry, and from field inspections and investigations. FDA also receives postmarket surveillance data from laboratory and statistical studies, 510(k)s, PMAs and PMA supplements, and mandatory and discretionary postmarket surveillance studies.

During FY 93, FDA improved its postmarket management capabilities by establishing a new Office of Surveillance and Biometrics (OSB) within CDRH, which combines all the statistical, epidemiological, and postmarket studies functions from the Office of Science and Technology (OST) with all the surveillance and clinical evaluation activities from the Office of Compliance and Surveillance (OCS). This merger enables FDA to increase the interaction of all its postmarket components, resulting in more scientifically sound and timely assessments of potential and actual public health problems. As a result of its accumulation and analysis of postmarket surveillance data, FDA issued four safety alerts and notices in 1993 advising health care professionals, professional organizations, manufacturers, and Federal agencies about problems associated with particular medical devices. The medical alert and notices listed steps that health care professionals could take to minimize potential problems.

6. Enforcement

FDA enforces numerous regulations to protect the public from unsafe or ineffective medical devices and radiological products. FDA takes various regulatory actions to rectify problems that occur and to serve as a deterrent against future violations of the Federal Food, Drug, and Cosmetic Act. In FY 93, FDA acted on the following enforcement and legal proceedings: 52 seizures; 13 injunctions; 10 civil penalties cases; 7 prosecutions/grand juries; 544 warning letters; and 436 recalls involving 851 products. In addition, FDA issued two letters to the medical device industry to inform the companies about current enforcement activities and to clarify certain enforcement policies and programs.

During FY 93, FDA reorganized the structure of its enforcement capabilities within CDRH along product lines into product teams. This change allows FDA to directly address device problems by allowing each product team to develop a high level of expertise and understanding of the specific devices. FDA is also focusing more attention on multi-site corporate compliance efforts to determine whether manufacturing problems are isolated or rampant throughout the corporation.

7. Risk Assessment

Risk assessment activities are important because they enable FDA to optimize protection of public health by focusing efforts where they are most needed. Data gleaned from the assessments provide a sound scientific basis for making regulatory decisions. Many variables may adversely affect the performance of a medical device or radiological product such as: adverse toxic reactions; faulty product design; manufacturing problems; materials degradation; and user errors. These problems can produce risks to both patients and health professionals.

FDA has continued to develop risk assessment methods for medical device problems. In FY 93, the Toxicologic Risk Assessment Committee evaluated the risk which would result from residues of ethylene oxide, a gas used to sterilize medical devices. The analysis provided the scientific basis for continued work with Europeans toward an acceptable International Standards Organization (ISO) standard. FDA scientists also expanded work with other Public Health Service scientists serving on the Committee to Coordinate Environmental Health and Related Programs' (CCEHRP) Risk Assessment and Risk Management Subcommittees. Here scientists participated in the ongoing review of the EPA reassessment of dioxin risks.

FDA engineers have extended their study of the effects of radiofrequency (RF) electromagnetic interference, which begun with infant apnea monitors, to an examination of interference with electrically powered wheelchairs. Sudden starts or uncontrollable movements of electrically powered wheelchairs have resulted from radiofrequency signals in the environment, particularly from communication devices. FDA has obtained powered wheelchairs and is examining their susceptibility to frequencies and field strengths. FDA is working with the manufacturers and an American National Standards Institute (ANSI) accredited standards organization to develop test methods to minimize this hazard.

FDA has continued its involvement with other government agencies set up under the Federal Coordinating Committee on Science, Engineering, and Technology (FCCSET). During FY 93, FDA planned the first of three national conferences. The conference, which will be held in FY 94, will bring together government and private sector groups to develop specific implementation plans for a

national device retrieval and analysis program. One important result of the conference will be agreement on methods of analysis for medical devices explanted from patients. Development of accepted methods of analysis will help scientists to assess critical device properties in actual lifetime experience (e.g. maintenance of mechanical function or degradation under wear).

9. Small Manufacturers Assistance

The Medical Device Amendments of 1976 specifically require FDA to provide technical, nonfinancial assistance to small manufacturers of medical devices. The device industry poses special challenges because of its mix of small "cottage industries" and large corporations. By providing assistance to manufacturers, FDA can improve the safety and effectiveness of all devices by improving compliance with regulatory requirements.

During FY 93, FDA's Division of Small Manufacturers Assistance (DSMA) handled more than 71,000 telephone calls requesting information, sponsored or participated in 11 workshops and 3 conferences, and published a variety of educational materials. Among the publications developed or reprinted were the Regulatory Requirements for Medical Gloves and the Premarket Approval Manual. In addition, FDA responded to 120,000 requests for medical device and radiological product publications.

In FY 93, FDA's DSMA established retrieval systems which allow easy access to the latest information on operating policies and procedures for manufacturers and others who are interested in the regulatory requirements for marketing medical devices and radiation-emitting electronic products. These DSMA-directed retrieval systems are:

- 1) Flash FAX - an automated system that allows the requestor to access device-specific guidance documents via FAX machine 24 hours a day, 7 days a week by using a touch-tone phone and following system prompts.

- 2) Public Docket - an arrangement for viewing and photocopying hard-copy documents at the FDA Public Reading Room. If a personal visit is not possible, hard copies of documents can be obtained by mail through a Freedom of Information (FOI) request.

- 3) Electronic Docket - an automated version of the public docket, available by computer terminal and modem, which offers a wide range of material from medical device regulations to talk papers and press releases.

In addition to these systems, DSMA has an inventory of 1,000 documents which are available to the public upon request.

10. Mammography Quality Standards Act of 1992 (MQSA)

MQSA was signed into law on October 27, 1992 to address the public health need for safe and reliable mammography. The Act requires all mammography facilities to be certified by the Secretary of Health and Human Services as meeting quality standards for mammography in the areas of equipment, personnel, quality assurance, record keeping, and reporting. After October 1, 1994, it will be unlawful for any facility to perform mammography without a certificate.

The Department of Health and Human Services officially delegated the responsibility of implementing MQSA to FDA in June 1993. Since that time, FDA has:

- Established a new Division and appointed a program director to ensure that the MQSA objectives are effectively and efficiently pursued.
- Chartered the mandated National Mammography Quality Assurance Advisory Committee.
- Began negotiations with the individual States to establish an effective facility inspection program.
- Began development of an inspector training and qualification program.
- Developed specifications and began procurement proceedings for equipment that will be used for field testing, instrument calibration, and data processing.
- Conducted a public conference on MQSA in September 1993 to communicate the intent, purposes, and scope of the Act, to identify issues, and to obtain recommendations concerning quality standards.
- Published interim regulations in the Federal Register setting requirements for accreditation bodies and quality standards for mammography facilities.
- Worked with Congress to draft technical amendments (effective December 1993) which corrected problems with the original Act.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

STATUS OF PROGRAM

During the past year, NCTR has continued to systematically integrate its research into areas of regulatory concern across FDA. NCTR scientists, in consultation with FDA colleagues, have focused their research efforts on two major areas: Applied Toxicology, which focuses on improving the risk assessment capability of FDA; and Methods Development, which specifically addresses immediate needs in the area of pre-market review and post-market surveillance assessment. NCTR's Science Advisory Board (SAB), which includes *ex officio* scientific liaisons from each of the other FDA centers and ORA, has reviewed the research ongoing in five of nine NCTR programs. NCTR has gained from these reviews both in affirmation of the quality of science at NCTR and in valuable suggestions for enhancing and focusing programmatic functions.

Activities currently underway at NCTR include:

1. Continuation of NCTR/FDA research integration coupled with SAB subcommittee reviews of individual research programs. Scientists continue to address issues of public concern such as heavy metal contamination in health food supplements, the efficacy of disinfectants, and the role of folic acid in neural tube development.
2. Continuation of coordinated studies with CDRH to measure toxicity of biomaterials, i.e., mechanisms of tumor initiation by foreign bodies such as polyurethane foam breast implant materials and electromagnetic radiation.
3. Initiation of research at NCTR on the pediatric sedative chloral hydrate and the corn contaminant fumonisin B₁ in order to combine expertise between NIEHS/NTP and FDA/NCTR to improve the animal model for use in risk assessments for regulatory needs.
4. Continuation of the NCTR commitment to human resource development by investing in an extensive array of educational outreach programs encouraging the participation of students from high school through post-graduate personnel, particularly women and minorities, in research for public health.
5. Jointly developing with ORA a program of requirements for a compliance and analytical methods research laboratory.
6. Continuation of NCTR's commitment to scientific networking by fostering and extending interactions with other agencies (Interagency Agreements), academia (cooperative research), and industry (Cooperative Research and Development Agreements).

Selected Examples of Current Progress

1. Agency Research Integration

In an effort to improve Agency-wide research coordination, NCTR is continuing to wholly integrate its research into areas of regulatory concern across all FDA centers/ORAs. Aggressive action by FDA management, FDA center/field scientists, and NCTR have resulted in a research program structure upon which FDA/NCTR can continue to evolve a more relevant research program. NCTR has organized its research efforts into two major areas: Applied Toxicology, which focuses on improving the risk assessment capability of the regulatory agency, and Methods Development, which specifically addresses immediate needs in the area of pre-market review methodology and post-market surveillance assessment. These efforts have resulted in an increasing impact on regulatory decisions. Position papers and/or data have been presented to address the risk of breast implants, effects of tamoxifen on the reproductive tract, the role of folic acid in neural tube development, heavy metal contamination in health food supplements, and the efficacy of disinfectants. NCTR has also become the focal point for FDA neuroscience, which is an area of increasing concern within the Agency.

2. Toxicity of Biomaterials

Recently much public attention has been given to the controversy over the safety of silicone breast implants and the larger issue of the safety of biocompatible materials. It is the goal of NCTR's Solid State Toxicity Program to increase knowledge of the mechanisms of long-term toxicity of implanted materials and enhance the scientific validity of regulatory decisions. Comprehensive feeding studies using 2,4-Toluenediamine have identified a dose response in adduct levels in liver and mammary tissue; foam implant studies have also identified adducts. Characterization of these adducts is in process. Additional studies are being developed to identify potential genotoxic mechanisms of toxic effects associated with foreign-body implantation. Further tumorigenic studies are also in development. In addition, more sensitive methods for detecting potential adverse effects from low levels of electromagnetic radiation have been developed and are being applied to a fuller understanding of the potential for harm associated with some consumer products.

3. Comprehensive Science-Based Bioassessment

Standard carcinogenicity testing is a costly, time-consuming process that at times does not expedite or support the regulatory process, nor does it adequately explain events that occur in humans. Due to its limitations, government, academia, and industry are predisposed to exploring new, innovative approaches for improving the animal model for use in risk assessment. To solve

this problem, FDA/NCTR, building on a strong toxicology research base coupled with enhanced intra-agency participation, and in coordination with NIEHS and the National Toxicology Program, has initiated a comprehensive program using the pediatric sedative, chloral hydrate, and a potent natural toxin found on corn, fumonisin B₁, to improve the standard animal carcinogenicity assay. The new system will utilize state-of-the-art technology and non-traditional techniques to better predict public risk and to bring the expertise of a larger number of scientists from other agencies to bear on the effort.

4. Human Resources Development

There is nation-wide lack of qualified math and science students, particularly among women and minorities. NCTR has conducted programs to improve math and science education in Arkansas. Several different programs have been implemented at NCTR that range from high school students (AEGIS) and high school teachers (STRIVE), through undergraduate-level personnel (NCTR Summer Student Program and Stay-in-School Program), and ending with post-graduate level training (INTOX, ORISE, Staff Fellow, and Visiting Scientists programs). Through these special employment programs, aimed primarily at women and minorities, NCTR provided career development opportunities for as few as 20 (1985) and as many as 195 (1992) participants. Currently, 142 trainees are participating in research programs at NCTR. Additionally, NCTR and ORA have assisted the University of Arkansas at Pine Bluff (a historically black university) with the development of an undergraduate program in regulatory science which is being funded by a grant from USDA.

5. ORA/NCTR Initiatives

Development and initiation of ORA/NCTR long- and short-term initiatives continues to enhance and formalize research collaborations and coordination between NCTR and ORA scientific staff. These initiatives include joint participation in research planning, establishment of user groups to foster scientific discussion in highly technical specialty areas such as NMR and elemental analyses, scientific exchange and potential economy of scale for FDA in leveraging the NCTR resource to assist ORA in inter-library loans and development of analytical standards. NCTR's central location and unique physical plant also lend themselves to developing a training site and program for field analysts and investigators.

6. Technology Enhancement

With the continued explosion of science and technology and increased economic pressures, the FDA must be proactive in obtaining the latest technology in the protection of public health. Increasingly complex products including drug-food combinations, drug-device combinations, a highly diversified industrial base, and

advances in information technology, require FDA to work more closely with industry, academia, and government to leverage resources and enhance our world-wide competitive advantage. NCTR's strong technology base produces a healthy research environment conducive to innovation and the development of mutually beneficial international science and technology relationships.

NCTR conducts toxicology research in a comprehensive, state-of-the-art facility which is accredited by the American Association for Accreditation of Laboratory Animal Care, has licensed waste disposal capability, extensive information management capabilities, and productive research interactions with academia (collaborative projects), other government agencies (Interagency Agreements), and industry (Cooperative Research and Development Agreements).

PROGRAM MANAGEMENT

STATUS OF PROGRAM

This program involves FDA's central program direction and administrative functions. In addition, it also is charged with issues which are agency-wide rather than single program concerns. The Agency will continue to place emphasis on the economic analysis of regulations, improving the exchange of scientific information, strengthening Agency compliance policy, and responding to Congressional and public inquiries. In particular, the Agency will continue its efforts to review and consolidate administrative support functions where possible and economical, and its efforts to make increased use of automation to enhance the quality and efficiency of support functions.

Selected Examples of Recent Progress

1. Freedom of Information

The impact of the FOI Act on agency resources has been substantial. A small central FOI staff is the focal point for coordinating responses, and for allocating manpower in all major components of FDA, to respond to approximately 47,978 requests a year.

FDA collected approximately \$812,813 in fiscal year 1993, compared to \$750,903 in 1992, and expended approximately 125 staffyears for FOI requests in 1993.

2. Strategic Planning

FDA continued to strengthen its ability to meet current and future challenges through the development of a comprehensive strategic plan for the Agency. The objective of the process was to identify ways to strategically implement programs, focus the organization on value-added activities, and to unleash untapped productivity potential. The plan incorporates a management model which involves an integrated design to structure management processes as well as reward and recognition systems. It provides a future vision for the Agency and links this to a mission statement and definite core strategies, strategic alliances, and infrastructure objectives.

3. Formula for Achieving Managerial Excellence (FAME)

The Office of Human Resources Management manages several Agency-wide career development activities, including the Formula for Achieving Managerial Excellence (FAME). FAME consists of the Interpersonal Skills Training Initiative and the Supervisory Development Program. FAME's goal is to

institutionalize a program of management development and to establish and maintain a well-trained cadre of Agency supervisors and managers.

4. Provision of Administrative Services

FDA has placed increased emphasis on the administrative management of the Agency with the goal of increasing effectiveness and efficiency in this area. The Reinventing Administrative Management Project (RAMP) and the Administrative Systems Automation Project (ASAP) were priorities in FY 1993. ASAP will serve as an umbrella for major reinvention initiatives and will facilitate an integrated set of Agency-wide information systems to replace existing manual, and outdated automated administrative systems throughout the Agency.

ADP SUMMARY
(\$000)

	1993 <u>Actual</u>	1994 <u>Approp.</u>	1995 <u>Estimate</u>	Increase or <u>Decrease</u>
<u>ADP Obligations by Accounts/Source</u>				
Salaries and Expenses...	\$53,405	\$54,000	\$54,000	---
<u>Distribution by Type of Expenditure</u>				
In-house				
Operations.	\$39,901	\$41,000	\$41,000	---
Outside Serv.	13,504	13,000	13,000	---
	\$53,405	\$54,000	\$54,000	---
<u>Distribution by Program</u>				
Foods.....	4,271	5,460	5,460	---
Drugs and				
Biologics.....	16,355	15,600	15,600	---
Veterinary				
Medicine.....	1,348	1,400	1,400	---
Devices and				
Rad. Products.	7,958	8,300	8,300	---
Nat. Ctr. for				
Tox. Research.	3,903	4,600	4,600	---
Program Mgt. ...	7,266	7,400	7,400	---
Field Activities	<u>12,304</u>	<u>11,240</u>	<u>11,240</u>	<u>---</u>
TOTAL.....	\$53,405	\$54,000	\$54,000	---

ADP APPLICATIONS

FDA utilizes ADP applications primarily in two areas: data collection and analysis in its laboratories; and information management of large volumes of data used for inspections, product application review, product monitoring, and other activities. By means of ADP applications, FDA is able both to conduct state-of-the-art scientific research and to maximize limited manpower resources in its regulatory efforts. At a time when many scientific discoveries and technological innovations are affecting the products FDA regulates, the application and use of modern automatic data processing capabilities is critical to FDA's effort to base its regulatory decisions on the best science available. Today, scientific laboratories extensively use ADP equipment to collect, process and analyze experimental data making it possible to obtain results almost immediately thereby saving hundreds of person-hours in many kinds of experiments.

Recent Accomplishments and Improvement Plans

The Food and Drug Administration (FDA) is developing a strategic systems plan designed to enhance its ability to execute its mission of protection of public health through product regulation. This strategic systems plan will have four areas of focus: managing the submission of product applications; facilitating access to information; supporting decision processes; and supporting administrative functions. Two major contracts will be developed to support this effort: Submission Management and Review Tracking System (SMART) and Agencywide strategic systems.

SMART - The goal of the SMART Program is to reduce the time required to bring new human drug, human biologics, and animal drug products to market through process improvement and the use of information systems technologies in the preparation, submission, and review of applications from industry. A common information architecture and systems approach will be used to link together the drugs, biologics, and animal drug review processes and their interfaces with the field activities supporting the product approval process. The Office of Management and Budget (OMB) selected SMART to be included in its Program for Priority Systems (PPS).

AGENCYWIDE STRATEGIC SYSTEMS - There will be numerous information systems initiatives which are directly supportive of the Agency's overall mission. These systems will cross organization boundaries within the FDA and will directly support the Agency's strategic plan in the areas of pre-market approval, post-market surveillance of regulated products, and administrative functions. Systems developed under this contract will be integrated with and will provide critical areas of functional support to the SMART System. Examples of such initiatives would include Agency-wide establishment/product registration, user fee administration, adverse effects reporting, and administrative systems.

The contract has been extended to continue the design and development of the Import Support and Information System (ISIS). This will be followed by a pilot test involving several Districts representing a cross section of the import activity. Upon completion of a successful pilot test, the system will be implemented nationwide.

Since ISIS must closely interface with the Field Information System (FIS), FIS is being redesigned into a relational database management system. The implementation of ISIS and the redesigning of FIS, renamed Field Accomplishments and Compliance Tracking System (FACTS), will extend over several years. The contract for the AGENCYWIDE STRATEGIC SYSTEMS will also support this conversion activity.

The major thrust of FDA's programs in future years will be the continued achievement of the Agency's primary mission--consumer protection. In pursuing this goal, the highest program priorities will be to improve and expedite the review processes for new human drugs and for medical devices. Increased emphasis will be placed on FDA's coverage of imports.

WEDNESDAY, MARCH 23, 1994.

FOOD AND NUTRITION SERVICE

WITNESSES

ELLEN HAAS, ASSISTANT SECRETARY, FOOD AND CONSUMER SERVICES, DEPARTMENT OF AGRICULTURE
WILLIAM LUDWIG, ADMINISTRATOR, FOOD AND NUTRITION SERVICE
GEORGE A. BRALEY, ASSOCIATE ADMINISTRATOR, FOOD AND NUTRITION SERVICE
KENNETH BRESNAHAN, ACTING DEPUTY ADMINISTRATOR, FINANCIAL MANAGEMENT, FOOD AND NUTRITION SERVICE
BONNY O'NEIL, ACTING DEPUTY ADMINISTRATOR, FOOD STAMP PROGRAM, FOOD AND NUTRITION SERVICE
JANICE LILJA, ASSOCIATE DEPUTY ADMINISTRATOR, SPECIAL NUTRITION PROGRAMS, FOOD AND NUTRITION SERVICE
MICHAEL FISHMAN, STAFF OFFICE DIRECTOR, OFFICE OF ANALYSIS AND EVALUATION, FOOD AND NUTRITION SERVICE
STEPHEN B. DEWHURST, BUDGET OFFICER, DEPARTMENT OF AGRICULTURE

Mr. DURBIN. Good morning. We would like to welcome this morning representatives from the Food and Nutrition Service of the U.S. Department of Agriculture. Ellen Haas, Assistant Secretary; Bill Ludwig, Administrator of Food and Nutrition; George Braley, Associate Administrator; Ken Bresnahan, Acting Deputy Administrator, Financial Management; Bonny O'Neil, Acting Deputy Administrator, Food Stamp Program; Janice Lilja, Associate Deputy Administrator, Special Nutrition Programs; Michael Fishman, Staff Office Director; and our constant companion, Steve Dewhurst.

Secretary Haas, thank you for joining us this morning. We have your statement which will be made part of the record. We invite your testimony at this point.

Ms. HAAS. Thank you very much, Mr. Chairman and members of the Committee.

I am very pleased to be here today to offer the Administration's vision for our programs in the Food and Nutrition Service for the coming fiscal year. We appreciate the opportunity to discuss President Clinton's and Secretary Espy's convictions that all Americans, especially our children, should have access to food that is nutritious and healthful.

I would like to introduce Mr. William Ludwig, Administrator for the Food and Nutrition Service—FNS, who is with me here today, and enter his biographical statement along with mine into the record.

Our budget request mirrors President Clinton's efforts to put children, nutrition, and health at the top of the Nation's agenda. The Food and Nutrition Service's appropriations for the current fiscal year totals \$39.5 billion, including a \$2.5 billion reserve for the

Food Stamp Program. The programs have had, and continue to have, strong bipartisan support for their traditional roles of providing access to food for needy Americans. At the new USDA, feeding hungry people is a top priority. Secretary Espy and I are committed to fighting hunger.

We are staunch supporters of the programs we administer. In 1995, 65 percent of USDA's budget will be dedicated to the 15 food and nutrition programs that I oversee. The fiscal year 1995 budget requests \$40.3 billion for the administration of USDA's food assistance programs, an increase of nearly \$1.0 billion above our Fiscal Year 1994 level.

Another way that USDA is fulfilling its commitment to fighting hunger is through the Mickey Leland Childhood Hunger Relief Act, which became law last year. The President's budget requests \$300 million to continue implementing the Leland Act in the Food Stamp Program. I have set up a task force to expedite the implementation of those regulations.

But we also must recognize that changing the way that we deliver Food Stamp benefits through modern technology with the use of electronic benefits transfer—EBT—is a priority, and an important one for both Secretary Espy and the Administration.

EBT, as you know, will replace the inefficient paper coupon system. It has been shown to be cost-effective, and has major implications for program integrity and improvement.

In fact, in the last year, Congressman Skeen, I was pleased to go to New Mexico when we released the results of the report, which showed how cost-effective EBT can be, and how it reduces diversion and losses in the Food Stamp Program. It provides dignity for recipients, more convenience for retailers, and more accountability for program administrators.

Working with our other Federal agency partners in the Department of Health and Human Services and Treasury, our goal is to make EBT nationwide, with one card, user friendly, across the government.

This budget requests \$10.6 million to continue to move aggressively toward implementation of EBT. The budget also provides funding for improvements in program integrity, which we believe are essential in the delivery of Food Stamp Program benefits.

The President's budget is a budget that invests in children. President Clinton's commitment to achieve full funding for WIC ensures that by the end of fiscal year 1996 every eligible woman, infant, and child who seeks the benefits of WIC will be able to receive them.

Mr. Chairman, I would like to thank you for your tremendous diligence and tireless leadership toward the goals of full funding for the WIC Program. Our budget calls for \$3.6 billion which is an increase of \$354 million, or an 11 percent increase above the 1994 budget. This increase will help to fund an additional 700,000 participants per month, bringing average WIC participation to approximately 7.2 million participants each month.

WIC has been extremely successful, in part, because nutrition education is an integral part of that program. We need to build on that initial investment in our children's health.

Eating habits are firmly established by the age of 12. So programs that deliver meals to children become a critical tool for developing life-long dietary patterns.

The Department of Agriculture has a national health responsibility in this area, so we have been leading a national effort to improve the nutritional standards of the meals that we serve to school children every day.

We serve 25 million children every school day in more than 92,000 schools. Half of those meals go to low-income children, and may be their only nutritious meal of the day. Children—especially poor children—need to get essential numbers of calories, vitamins, and minerals for physical and cognitive growth.

In addition, childhood obesity and other diet-related problems are particularly severe for low-income minority children, and have long-term health consequences. Secretary Espy and I both understand that we have a special responsibility to provide meals to children which make a positive contribution to their health.

We have traveled the Country, we have held hearings, and we have heard testimony from medical and health professionals who talked about the critical link between diet and health. We have had 350 witnesses, and we had 2,300 written comments. The hearings and the public comment process have provided us with a compelling call for change.

USDA is planning a comprehensive, integrated approach to meet the challenge of providing nutritious, appealing school meals as economically as possible.

As we develop this important approach, we are guided by five principles. First, and foremost is healthy children. We must provide our nation's children with access to a school lunch and a school breakfast program that promotes health, and meets the Dietary Guidelines for Americans. As you know, Mr. Chairman, the Dietary Guidelines are our nation's policy for what constitutes a healthful diet. Since 1980 they have been jointly issued and revised by the Department of Health and Human Services and the Department of Agriculture.

Our second principle is customer appeal. If kids do not like the food, if it does not taste good, and if it does not look good, they are not going to eat it. We need to support the changes we propose with a national campaign of nutrition education, aimed at children—using the media they understand in a language that they speak.

Third is flexibility. Throughout our hearings, school food service professionals testified about the complexity of administering the school meal programs. We need to reduce the burden of paperwork and streamline administration. We need to recognize that there are major economic and regional differences among schools, and we need to offer schools flexibility in designing menus that meet Dietary Guidelines.

Our fourth principle in these changes is investing in people. We have heard a consistent call from schools for training and technical assistance, and also for building skills among children for wise food choices.

To accomplish this, the fiscal year 1995 budget requests approximately \$30.8 million for nutrition education, training, and tech-

nical assistance, to help schools comply with the recommendations of the Dietary Guidelines. Finally, we must look for innovative ways to maximize our resources.

Mr. Chairman, the domestic food assistance programs that I have the privilege and honor of administering provide millions of needy children and adults with access to the nation's abundant food supply. These programs help nearly 40 million needy Americans, and put food on their plates to achieve nutritious diets. We estimate that one out of every six Americans is served through the programs managed by the Food and Nutrition Service. We must continue to provide access. With what we know now about the link between diet and health, we must extend the reach of these programs by providing the education and assistance necessary for all Americans to make nutritious food choices. The fiscal 1995 budget request of \$40.3 billion for food assistance programs is essential if we are to reach this important goal.

At this time, I would like to call on Bill Ludwig, our Administrator, if we have your permission, to present his statement.

Mr. DURBIN. Please. You may proceed.

Mr. LUDWIG. Thank you, Mr. Chairman. It is a pleasure for me to appear before this subcommittee to discuss the 1995 budget proposed for the food assistance programs administered by the United States Department of Agriculture.

The mission of the Food and Nutrition Service is to alleviate hunger and safeguard the health and well-being of the nation through the administration of domestic food assistance programs and nutrition education. FNS works in partnership with state and local governments to perform this mission.

The Food and Nutrition Service's appropriation represents over 60 percent of the budget authority of the U.S. Department of Agriculture for Fiscal Year 1994. Over two-thirds of the FNS appropriation is used to fund the Food Stamp Program. Over 99 percent of the total appropriation is for recipient benefit payments or grants to states for the administration of the program.

Less than 1 percent of the overall appropriation pays for the direct Federal administrative expense of the agency. The Food and Nutrition Service employs less than 2 percent of the people within USDA.

For fiscal year 1994, the Food and Nutrition Service's appropriation totaled \$39.5 billion, including Food Stamp Program reserves. This level of funding allows FNS to emphasize program integrity and concentrate on improving efficiency in the delivery of benefits.

Major areas of emphasis include the implementation of the Mickey Leland Childhood Hunger Relief Act, implementation of electronic benefits transfer, implementation of strategies to increase enhanced Food Stamp Program retailer integrity, and implementation of strategies to reduce errors caused by recipients and State agencies within the Food Stamp Program.

Further, we emphasize continuing efforts toward achieving full funding for the WIC program to ensure that all eligible persons can be served by the end of fiscal year 1996; promoting breast feeding, immunizations, smoking cessation, and developing an exit counseling brochure for those recipients no longer eligible for the WIC program.

We are also undertaking a comprehensive initiative to promote the health of children by improving the nutrition quality of school meals, so that they meet the U.S. Dietary Guidelines; and lastly, continuing operations in expanding the homeless demonstration project to evaluate feasibility of providing Federal Child Nutrition Program funds for meals served to children in homeless shelters.

Mr. Chairman, we appreciate this opportunity to discuss the fiscal year 1995 budget proposed for the Food and Nutrition Service. This budget reflects the highest overall funding ever requested for the domestic food assistance programs.

The amount requested will enable us to serve record numbers of participants in our programs. The President and Secretary of Agriculture clearly make nutrition a top priority as a part of the goal to improve the health of all Americans.

Food assistance to the needy is inseparable from nutrition and health, and we have increased our commitment to provide program support to fight hunger and improve the health of America's neediest citizens.

The budget I present to you today recognizes the critical importance of continued support for the food assistance programs, and reflects the President's and the Secretary's goals for the Food and Nutrition Service.

I cannot emphasize enough the importance of these programs for needy Americans. This budget represents \$40.3 billion in new budget authority for fiscal year 1995, including Food Stamp Program reserves. This is an increase of almost \$1 billion over the fiscal year 1994 appropriation level. While some of this increase is driven by inflation, it is a declaration of the importance that USDA places on the health of our citizens.

The most significant increase has occurred in the WIC Program, and the mandatory Food Stamp account. For the Food Stamp Program, we are requesting an appropriation of \$27.7 billion, including reserve funding to ensure that funds are available to meet any unmet needs.

The amount of this request is based on our best projections under current law and government-wide economic assumptions. We are asking for the Committee's consideration for an appropriation that would include a \$2.5 billion reserve in the event that program growth overwhelms our current program estimates.

I know that you and I agree, Mr. Chairman, on the critical importance of the Food Stamp Program as a life line for needy people.

The 1995 budget proposal will allow FNS to continue to move aggressively toward the implementation of electronic benefits transfer where cost effective. Continued support of EBT underscores Secretary Espy's and Assistant Secretary Haas's commitment to improve efficiency and integrity in the Food Stamp Program.

It was highlighted in a report of Vice President Gore's National Performance Review, and recent studies have shown that EBT can lower operating costs. As an example, one study recently showed that government issuance costs dropped, cost to retailers dropped, and recipient costs dropped such as those associated with lost benefits.

Of equal importance to the cost effectiveness of EBT is the effect that EBT has on Food Stamp recipients. In each of our evaluations,

recipients have embraced this new benefit delivery system as one that removes the stigma of using paper stamps and one that affords them much more security over their benefits than a paper coupon system.

Today there are approximately 224,000 households using over \$40 million in Food Stamp benefits each month via EBT at 3,750 retail food stores. Throughout fiscal year 1994, we expect to see EBT increase as projects expand to serve about 270,000 households by delivering \$49 million in benefits each month.

In fiscal year 1992, 8.19 percent of the Food Stamp benefits were over-issued, and 2.5 percent were under-issued, for a total error rate of 10.69 percent. This represents a net loss to the program of \$1.2 billion.

We must continue to pursue improved payment accuracy rates as a high priority. In an attempt to assist state efforts to improve payment accuracy, FNS is requesting an increase of \$1.0 million for error reduction activities which will provide increased Federal presence in working with the states to substantially improve their management and oversight of the Food Stamp Program.

The Mickey Leland Childhood Hunger Relief Act expanded benefits to those in most need, but also toughened penalties for people who try to cheat the system. Several initiatives are proposed in this budget to increase the integrity of the Food Stamp Program.

We are working hard to strengthen the Agency's debt collection methods. One method being tested collects over-issued Food Stamp benefits from Federal income tax refunds of individuals who received such excess funds because of fraud or errors.

In 1992, the first year of the test, we collected over \$3 million in offsets from the two states involved. Voluntary payments provided an additional \$400,000. In 1993, we added seven states, and collections both offset and voluntary payments totaled \$8.5 million.

We have added another 12 states in 1994, which brings us to a total of 21 states. We estimate that program-wide use of tax offsets would result in \$25 million to \$40 million collected each year.

The budget request for nutrition assistance for Puerto Rico is \$1.143 billion, an increase of \$52 million over the amount appropriated for fiscal year 1994. This is the maximum amount authorized.

In keeping with the President's commitment to reach full funding for the WIC Program by the end of fiscal year 1996, the fiscal year 1995 budget proposes a substantial funding increase for WIC. We appreciate the consistent support that this committee has shown for WIC over the past several years.

For fiscal year 1995, the request totals \$3.6 billion compared to \$3.21 billion appropriated for this fiscal year. Within this increase, WIC's average monthly participation would increase to about 7.2 million, an increase of about 700,000 from the projected fiscal year 1994 average.

This increase reflects a fundamental commitment to the welfare of children whose circumstances fail to provide the kind of nutrition needed for good health and normal growth.

Food assistance and nutritional assistance are inseparable issues, and are closely linked to the Administration's health care priorities. Recent studies have demonstrated that low income persons,

those most likely to participate in the food assistance programs, are at greatest risk for diet related diseases. That makes WIC that much more essential as it provides nutrition education and counseling to those with special needs and improves their nutritional status at a fraction of the cost of other programs.

Infant formula rebates negotiated by states and manufacturers are a critical component of the cost effectiveness of the WIC Program. Through expanded multi-state bidding, WIC has achieved greater savings than ever. The WIC infant formula rebate revenues for fiscal year 1994 are projected to be over \$900 million, and will support nearly 1.5 million participants, about one-fifth of the projected WIC participation.

USDA has traditionally played a significant role in promoting and supporting breast feeding among WIC participants. In recent years, USDA has actively undertaken a number of initiatives to further support this important health practice, including sponsorship of a breast feeding promotion consortium of health professionals, government and advocacy organizations, mutually interested in breast feeding.

USDA is developing an initiative to promote breast feeding among the general public and others who influence a woman's infant feeding decision. Our ultimate goal is to increase the level to at least 75 percent of the proportion of mothers who breast feed their babies in early life.

For the last three years, the USDA has worked very closely with the Centers for Disease Control and Prevention to increase immunization rates among pre-school-aged WIC participants. Numerous activities are occurring at all levels of the program operation to promote timely immunizations.

These various strategies seem to be having a positive effect. In the past two years, FNS has developed over \$1 million worth of materials, videos, professional guides, posters, and participant brochures to meet a 1988 legislative mandate that WIC provide information on the effects of alcohol, tobacco, and other drugs used during pregnancy.

A 1994 Congressional directive specifically requires WIC to give women, as they leave the program, information on several nutrition and health issues, including the dangers of tobacco and exposure to secondhand smoke. Efforts to meet the 1994 directive include updating a brochure entitled "How WIC Helps," directed to pregnant women, developing a brochure entitled "After You Deliver, Health Tips for Moms," and purchasing from the March of Dimes, for distribution in WIC clinics, a brochure that focuses on the dangers of smoking during pregnancy, and the harmful effects of secondhand smoke on children.

For the Child Nutrition Programs, we are requesting a total of \$7.5 billion for fiscal year 1995. These funds are required to meet the payments authorized under current law for subsidies providing free, reduced price, and paid lunches, breakfast, and snacks to eligible participants in schools, summer programs, and child and adult care centers.

As I am sure the Committee is aware, several provisions of the School Lunch and Child Nutrition Act expire at the end of fiscal year 1994.

This budget proposes to increase spending in the Child Nutrition Programs for education, training, and technical assistance for providers and children to prepare and eat school meals which meet the recommendations of the Dietary Guidelines for Americans.

In recent years, there has developed a scientific consensus that we must be concerned with more than recommended dietary allowances. The Dietary Guidelines for Americans are the Federal policy on what makes a healthy diet. They were established in 1980 by USDA and Department of Human Services. In 1990, the Dietary Guidelines were revised to include recommendations that not more than 30 percent of calories come from fat, and not more than 10 percent of calories come from saturated fat.

Reinforcement of this recommendation to apply these limits to the diets of children was issued by the American Academy of Pediatricians in September 1992.

A recent USDA study of school meals showed that we are doing an excellent job of providing one-third or more of the RDA for essential vitamins and minerals and the recommended number of calories.

The budget proposal includes an increase of \$18.4 million to provide nutrition education tools for states, to increase FNS' capacity to provide technical assistance to states, and to help school food authorities comply with the Dietary Guidelines.

In our four public hearings, we heard a consistent call for training and technical assistance. If food does not look good and taste good, children will not eat it. So we want to invest in the people who participate in and administer these programs.

The Nutrition Education and Training Program, NET, develops nutrition education programs and instructs food service workers and teachers in nutrition and health. FNS proposes a total of \$10.3 million for the NET, the same level of funding as for fiscal year 1994. This NET funding is an important component of a comprehensive multi-year initiative to implement the Dietary Guidelines in the Child Nutrition Programs by the year 2000. NET is needed to teach children to make healthful food choices and to assist food service staff in producing school meals that comply with dietary guidelines.

The fiscal year 1995 budget will provide meals to approximately 25 million children daily in the National School Lunch Program, over half of whom received their meals free or at a reduced rate. The 1995 estimate for the School Lunch Program is \$4.4 billion, up from \$4.3 billion in 1994.

The School Breakfast Program will provide meals to approximately 5.9 million children, of whom more than 5 million will receive these meals free or at a reduced rate. Estimated spending will total over \$1 billion for the breakfast program in 1995, up from \$950 million in 1994.

The Child and Adult Care Food Programs serve approximately 2 million children and adults on a daily basis. Anticipated spending for the program is \$1.6 billion in 1995, up from \$1.5 billion in 1994. About one-half of child care meals will be served in day care centers including Head Start Centers, and one half of the meals will be served in family day care homes.

The Summer Food Service Program last summer served meals to just over 2 million children each day. Anticipated spending for the summer program will total \$256 million, up from \$232 million in 1994.

For fiscal year 1995, the President's budget requested \$94.5 million for the Commodity Supplemental Food Program, the same as was requested in fiscal year 1994, and somewhat less than the fiscal year 1994 appropriation.

The Food Donation Programs for Selected Groups support the Food Distribution Program on Indian Reservations, the Nutrition Program for the Elderly—NPE—commodities for soup kitchens, the remaining support for the trust territories in the Pacific, and disaster assistance. The budget request is \$230 million.

The budget increases direct spending for soup kitchens and food banks to help offset a decrease in other commodities available for donations. The request would fund a food assistance program for American Samoa for the elderly, blind, and disabled, which will help persons not helped by the Child Nutrition Program block grant already functioning there. The budget requires a slight decrease in per meal reimbursements in NPE, but maintains participation at the Fiscal Year 1994 level.

The budget requests \$40 million in administrative funds to continue the TEFAP distribution network. The TEFAP network will allow the distribution of bonus commodities, and facilitate efforts to help provide for the basic food needs of low income Americans. Funds would allow the continued distribution of prepared meals supported by USDA commodity donations to soup kitchens and food banks, and household distributions of commodities provided by a variety of private sources.

Funds are not requested to purchase commodities for The Emergency Food Assistance Program, in part for budgetary reasons, but also in recognition that Food Stamp benefit levels have increased. States will continue to receive bonus commodities for distribution as well as administrative funds to support their infrastructure. FNS will work with industry and community groups to promote and encourage increased food donations as well as referrals to the Food Stamp Program, which is our mainstay in the fight against hunger.

Critical to the achievement of all of these objectives are the administrative funds of the agency. For fiscal year 1995, we are requesting \$107 million, a decrease from \$784,000 from fiscal year 1994. This level of funding is critical to allowing the Agency to meet its mission and maintain program operations at efficient and effective levels.

Mr. Chairman, we have made extraordinary efforts in the Food and Nutrition Service to meet the challenges of growing food assistance programs, at the same time, working harder with less. The level requested in this budget will support our mission of safeguarding the health and well-being of our nation through the administration of the domestic food assistance programs.

This summarizes the fiscal year 1995 budget request of the Food and Nutrition Service, and I will be happy to answer any of the committee's questions.

[CLERK'S NOTE.—Biographical sketches for Ms. Haas and Mr. Ludwig appear on pages 539 through 540. The statement of Ms. Haas appears on pages 541 through 548. The statement of Mr. Ludwig appears on pages 549 through 577. The explanatory notes appear on pages 578 through 715.]

WIC FULL FUNDING

Mr. DURBIN. Thanks for your testimony, Mr. Ludwig and Ms. Haas. We understand that about 40 percent of the children born in the United States are WIC clients, which is a statistic that most people would be surprised to hear. This subcommittee and Congress have been committed to full funding of WIC, because of our belief in this program.

Starting last year though, I held meetings with advocates of the WIC program to express a concern I have. My concern is this. I have a genuine fear that we are going to overload the administrative system for WIC. As we push more and more dollars into the program in an effort to move toward this full funding target, we may in fact do a disservice to the program.

Last year this subcommittee added \$350 million for WIC expansion in fiscal year 1994. In order to provide this \$350 million, we had to make cuts in other areas. We are still striving for the goal of full funding and that will call for even more spending. The budget request includes another \$350 million this year to keep ahead of our goal or at least continue to move toward our goal of full funding.

Having said that, though, the statistics coming back from the Department about the WIC program unfortunately confirm some of my fears. In years gone by, it has not been unusual for the WIC program to have anywhere from \$60 to \$75 million in unspent funds. These are allocations to States which could not be spent in those States. They could not absorb the money as fast as we were sending it to them.

Now this year, fiscal year 1994, with an increase of \$350 million coming into the WIC system, you have doubled your estimate of unspent funds to \$120 million. In other words, we are trying to force feed these local WIC and State programs faster than they can absorb the funds. Many states are crying uncle and sending the money back.

Now I know you will find other States that can absorb more in the process, but I worry, as I look at this full funding goal, that we are not stepping back and asking what is the most sensible way to put this money into the hands of people who can use it to increase the number of mothers and children who are served by the program.

As we head for this full funding goal, are we sensitized to the administrative problems that are created at the local and State level?

Ms. HAAS. Mr. Chairman, we certainly share your concern. This is a very, very important priority for all of us—that the program meet its goals of serving all eligible women, infants, and children, and that we run this program with the utmost of program integrity, so it will live in the future.

We have done several things. To begin with, we began very early last year after the President's announcement of the goal of WIC full funding, to meet with those in the WIC community to do strategic planning.

We are seeing that there is great variance across states. Some states like California have had great population growth and have a large number of eligibles not participating. Then other states like the ones you talked about could not use the funds because they did not have that same level of growth.

REVISION OF WIC FUNDING ALLOCATION FORMULA

We are revising the funding formula to take into consideration those variances in growth across states because all States are not the same. WIC is a national program, but across States, there are great differences in who is still eligible and not participating in the program. I think that the revised funding formula will have a very big impact on increasing funding to States with the greatest need.

At the same time we are devoting research and evaluation funds to look at our eligibility criteria, to be on top of that as well.

We recognize participation growth as a very important issue. I believe that we can meet the President's goal of WIC full funding by the end of 1996, and we can do it in such a way that we maintain the integrity and cost-effectiveness of this program.

Mr. DURBIN. I think we share that goal. But we scraped to find \$350 million to put into the WIC Program this year, to move toward full funding. When we did that some \$60 million more came back out of the system. They said we cannot absorb it. So now we are being asked to scrape again from other programs for another \$350 million over and above fiscal year 1994. What is going to be the reaction again? Is the system going to reject this and say we cannot absorb it again?

Ms. HAAS. No, the system will be ready to use the requested increase because of the changes that I spoke of concerning revision of the funding formula.

Maybe George or Bill can add to that.

Mr. LUDWIG. Yes. This is a real concern of ours. In fact, yesterday I talked to two different States about this issue.

When you look at it overall, about 4 percent of the total appropriation is coming back to us, and \$120 million is quite substantial.

We have looked at the current funding formula that was used in 1994, and what we basically found was that some of the States that did need additional funds, like Texas and California, did not receive them. We are revising the funding formula to take into consideration those States that are more needy, so that we will reduce the amount coming back to us. Yes, it is a genuine concern of ours, Mr. Chairman.

HOME VISITS IN OUTREACH

Mr. DURBIN. I have been invited for the last two years to an Aspen Institute weekend, a bipartisan weekend, to discuss children's issues. On this last occasion we discussed violence and children, and several of the people who were there and study children's issues suggested that one thing we could do, which might be a

breakthrough in terms of helping children, is to find some way to have more home visits and delivery of services at home.

This rankles some people who say, wait a minute, we are giving assistance away, and if people cannot even come out to get it, why in the world should we have to go looking for them?

In fact, what we are finding is, in some of the most dysfunctional families, some of the most trying circumstances, it really might be a good investment of our time to go looking for these folks and try to give them a helping hand.

I think that helping hand extends beyond nutrition. The fact that there is one-on-one counseling and outreach may mean for some families a turning point; some hope in an otherwise desperate life.

I have been looking at all the programs in USDA, and it seems that we have a lot of them that get close to that model, this outreach model, and you have talked a little bit about it here. WIC seems to me to be one of the areas we might consider this approach. Do you think that that is an opportunity we could avail ourselves of now under current WIC authorization, to have more home visitation, or is that something where you are going to need legislative authority and guidance?

Ms. HAAS. That is an interesting question. As we said earlier this year, the child nutrition reauthorization gives us an opportunity.

I also believe that the WIC nutrition education component, which is already integrated into the program gives us an opportunity to provide information about smoking cessation and immunization. It is a wonderful opportunity.

Outreach could not be more positive and more fitting. I do not see why we could not consider looking at some pilots to really see if this makes a difference. Are you suggesting that we do this as a complement to the counseling that is going on now?

Mr. DURBIN. Yes.

Ms. HAAS. And to really see if in a home situation, which reflects the value of WIC, we can promote the strong family values of health and nutrition.

Mr. DURBIN. I think that is a possibility.

The Extension Service has a Youth at Risk program that has a pretty broad mandate. Maybe that is something we could team up with. I have been told that in the Head Start program in many of my rural counties, the kids who are in Head Start who do not attend the Head Start centers, but are learning at home with a visiting counselor coming by are doing pretty well. In fact, they are keeping up with the kids in the centers.

So it strikes me that we have some models here and some opportunities to look at. I would like to work with you and see if we can take a look at that.

Ms. HAAS. Absolutely.

HAWAIIAN PINEAPPLE—BUY AMERICAN PROVISION

Mr. DURBIN. If I could move from WIC to something else for a moment.

My good and close friends, Congresswoman Patsy Mink and Senator Danny Akaka, have brought to my attention the fact that many of us who buy pineapple products today and buy brands like Dole and Del Monte mistakenly believe we are buying Hawaiian

pineapple, when in fact we are buying pineapple from Malaysia and Indonesia. In fact, at this moment Dole, one of the biggest names in the business, does not can any pineapple in Hawaii and any canned pineapple you buy from that company does not come from the United States. They only send fresh pineapples to the mainland.

There is only one canning company left in Hawaii that cans pineapple. It's on Maui.

Congresswoman Patsy Mink, as a young girl, used to work on the assembly line of this pineapple plant. I walked through it with her a few weeks ago, and they love her, as you can imagine, and she loves them. We are talking about 200 or 300 people working on Maui, primarily women and basically low-income jobs, but very important to their economy.

Congresswoman Mink asked me, as did the company, do you not have a Buy American provision in the School Lunch program? Why is it that they are buying pineapple products through Dole and Del Monte, products that comes in from Malaysia and Indonesia, when we have Hawaiian pineapple products available?

Now, we have taken a look at this and I think Congresswoman Mink has been in touch with you as well. I said to them, one of the most important considerations is the price we pay to become competitive. I do not want us to say we are going to buy Maui canned pineapple at any cost. We are not going to do that. They said, well, we are certainly willing to work within those guidelines. Incidentally, there is a Puerto Rican company that cans pineapple as well.

How do we follow the Buy American provisions in an instance like this, and make sure that School Lunch programs are buying Hawaiian pineapple as opposed to imported fruit?

Mr. BRALEY. We have met with Congresswoman Mink and discussed the possibility of buying Hawaiian pineapple through the commodity program. So there are some discussions underway.

In terms of the Buy American provisions of the commodity programs, we guarantee that the foods we buy are of domestic origin. It is a little more difficult in terms of local purchases. We would be happy to work with Ms. Mink and see if there are ways that we can let people know about the availability of pineapple from Hawaii.

Mr. DURBIN. Well, that is what it gets down to. We have got to get the message down to the state administrators of the program, as well as to the local school districts.

Now, I might add, to help things out a little bit, this company is stamping every can with a hundred percent Hawaiian on top. So if you go to the store and look at the cans, you are going to find, not the major brands but in the minor brands, 100 percent Hawaiian pineapple products. So it is something you can find.

Ms. HAAS. I want to give you a little bit of a different answer. In our effort to bring the health objectives into our School Lunch program so that they meet the Dietary Guidelines, as I mentioned earlier, we have requested \$31 million for training, technical assistance and nutrition education. One of the problems is that we have not been providing, or our children have not been eating, enough fruits and vegetables. Through the training and technical assist-

ance that we envision, we have an opportunity to also be talking about how to purchase fruits and vegetables, how to make them more a part of the school meals' menu, and I see that kind of training and technical assistance in a positive way, as a really important goal.

The other thing that I learned through the hearings is the need to encourage use of regional and seasonal fruits and vegetables, instead of having a national system, which really stresses having Washington apples go across the country. That would also encourage in the West the use of these pineapples as well.

Mr. DURBIN. Let us try to work on that.

Ms. HAAS. Good.

Mr. DURBIN. That will make Patsy Mink very happy, and I think she has a legitimate point. For the record, tell us what guidance do you provide to school food service authorities that are using Federal money to purchase commodities to assure they follow the Buy American provision?

Mr. LUDWIG. I will be happy to provide that information for the record.

[The information follows:]

Section 3(h) of the Commodity Distribution Reform Act and WIC Amendments of 1987 (P.L. 100-237) requires that recipient agencies purchase, whenever possible, only food products that are produced in the United States. Exceptions to this requirement are permitted when (1) recipients have unusual or ethnic preferences in food products; and (2) for such other circumstances as the Secretary considers appropriate. The legislation exempts those recipient agencies located in Alaska, Hawaii, Guam, American Samoa, Puerto Rico, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands from the buy American requirement because, given their locations, it would not be economically or logistically feasible to restrict their purchases to American-produced foods.

Under the authority granted the Secretary in the legislation, current Federal regulations exempt recipient agencies from the buy American requirement in instances when: (1) a desired product is not produced or manufactured in the United States in sufficient and reasonably available quantities of a satisfactory quality; or (2) the cost of a U.S.-produced food product is significantly higher than the foreign-produced counterpart.

Mr. DURBIN. What oversight or monitoring efforts do you have in place to make sure school districts obey the law?

Mr. LUDWIG. Compliance with the requirements of the Commodity Distribution Reform Act and WIC Amendments of 1987 (PL 100-237) is required as a condition of participation in the school feeding programs, just as compliance with all statutes and regulations is required. The Food and Nutrition Service provides all administering State agencies (SAs) with a prototype agreement to be used between the SA and a School Food Authority (SFA) participating in school feeding programs. This prototype agreement provides the terms under which SFAs may participate in the school feeding programs funded by the U.S. Department of Agriculture and includes compliance with PL 100-237.

The primary method of determining SFA compliance with provisions of their agreement and regulatory requirements is through on site reviews conducted by the SA. Under the National School Lunch Program and the School Breakfast Program regulations, the specific review of SFA purchases would be conducted in the review of expenditures from the SFA's nonprofit food service account. Food

purchases for use in the school feeding programs are made from this account.

The Food and Nutrition Service began oversight reviews of SA efforts to ensure recipient agencies implemented the Buy American requirement in Fiscal Year 1989 through the Management Evaluation Process. The most recent update of the Food Distribution Program Management Evaluation Guidance module, which will be issued within the next few weeks, will include Buy American monitoring for schools, charitable institutions and Nutrition Programs for the Elderly.

DIETARY GUIDELINES

While we are on the subject, Mr. Ludwig's testimony suggested that the current School Lunch program is not meeting Dietary Guidelines, and that it is pretty far off the mark.

Ms. HAAS. Right.

Mr. DURBIN. I do not want to misstate your testimony, but if I am not mistaken—

Ms. HAAS. Less than 1 percent of school lunches are meeting the Dietary Guidelines for Americans today.

Mr. DURBIN. School lunches exceed the Dietary Guidelines for fat by 25 percent; saturated fat, 50 percent; and sodium by 100 percent. Which takes us to an issue which we are bloodied but unbowed on, the whole question of mandating whole milk. [Laughter.]

Mr. DURBIN. Now, there is a reauthorization coming up.

Ms. HAAS. I notice the laughter.

Mr. DURBIN. There is a reauthorization coming up, if I am not mistaken, on the School Lunch program. What will be the administration's position on mandating whole milk? And I might add that the young lady in the picture behind me has skim milk on her tray. [Laughter.]

Ms. HAAS. She is setting a fine example.

Well, let me say we do not have a position at this time on milk in the child nutrition bill. However, let me speak to that issue, because I think it has really become the symbol in a lot of ways of our collective efforts to promote the health of children.

Really there is a larger issue, and that is in the overall meal pattern that exists today, and how we can move to one that over time meets the Dietary Guidelines.

Mr. DURBIN. Excuse me, Assistant Secretary Haas. You want to get cosmic on me here. I want to get specific.

Ms. HAAS. I know. And I am being very careful to be cosmic. [Laughter.]

Mr. DURBIN. Moving to another subject. [Laughter.]

Mr. THORNTON. I think you have been "touche'd."

Mr. DURBIN. Yes. We are going to keep fighting this battle. I think it is inconsistent to mandate whole milk in a situation where we know that it does not meet Dietary Guidelines. I do not want to take too much time here. I would like to talk to you for a moment about this Food Stamp program in American Samoa?

AMERICAN SAMOA NUTRITION ASSISTANCE PROGRAM

I understand the Secretary wants to create a program there, and he has the discretion to do it. We are concerned, though, that he

is doing it through a fund which seems a little bit unusual—funding it out of the food donations program as opposed to the food stamp appropriation. That has some budgetary significance, as Steve and others are aware of.

But tell me, if you will, why we should be starting a new program at a time when existing programs are being reduced because of budgetary problems?

Ms. HAAS. We did include the Samoa program in the food donations program, and we struggled for awhile on where the appropriate place was for this program, because it is unique and it is a very small program at that. So we are not creating a massive new program here. We are really trying to put it in a category and recognize the uniqueness of the program.

George, do you want to add to that, perhaps?

Mr. BRALEY. Yes. Mr. Chairman, the program in Samoa would not be like the Food Stamp Program in the States. It is very specifically targeted to elderly, blind and disabled, who number only a few thousand as potential participants, and certainly I think we would all agree they are in need of assistance.

In terms of the funding mechanism, we seriously considered funding the program out of the food stamp account and had some prolonged discussions with the Office of Management and Budget. Ultimately, because it was viewed as a discretionary increase, it needed to be funded out of a discretionary account.

The food donations account was the most logical and readily available account that we could choose. We do not believe that funding this program at an estimated \$2.7 million this year or \$5.3 million next year will adversely affect the services provided through other programs in that account.

Mr. DURBIN. Will it operate like the block grant in Puerto Rico or similar to it?

Mr. BRALEY. It is similar to that, and similar to a program in the Northern Marianas that we started several years ago.

ELECTRONIC BENEFIT TRANSFER AND FOOD STAMP FRAUD

Mr. DURBIN. I would like to direct my next line of questioning to Mr. Ludwig, if I might.

We think EBT is a good idea, but GAO has a report, and I do not know if you have seen their latest analysis, but it raises some questions about whether the electronic benefits transfer program in food stamps will in fact reduce fraud problems. They talk about the fraud that occurs with the initial interview, when people give fraudulent information to qualify for food stamps, and the fact that this is not addressed by EBT.

I would like to draw a parallel to an experience which you recently went through, which was shared with me by James Lee Witt, the head of FEMA, when the L.A. earthquake hit, and your agency decided, as it should have, to move in quickly with food stamp availability for eligible families.

Would you share with us what your experience was in Los Angeles when you opened up your doors to the world for people to come in, and sign up for food stamps?

Mr. LUDWIG. I will have to thank Mr. Witt next time I see him for mentioning me. [Laughter.]

You have asked several questions, and I would like to address them individually. Let us talk about EBT first.

EBT addresses fraud from the trafficking perspective. It will not have any great impact on fraud at the eligibility office where the recipient comes in and misrepresents her financial or his financial status up front.

There are some other things that we are looking at to hopefully address that type of fraud.

Mr. DURBIN. Could I interrupt you for just a second?

Mr. LUDWIG. Yes.

Mr. DURBIN. One of the suggestions is to try to coordinate the Food Stamp program with AFDC and other programs so we draw from a common data source and can have some consistent information, rather than each agency asking the same questions all over again. Is that being considered?

Mr. LUDWIG. Yes, sir. We have some memorandums of understanding [that we just entered into] with HHS and a number of other departments to share eligibility information, specifically on fraud.

We are trying to establish some databases on clients who have been disqualified due to fraud and that information will be available to all the States. So we are doing some things to address fraud from the eligibility standpoint.

EBT is designed specifically to combat the fraud associated with trafficking.

Now, will it eliminate fraud there? Not entirely. It gives us the opportunity to police it much better. Right now we have no way to track a coupon. It would be like trying to track a dollar everywhere it has gone through the system, by the time it returns to the Federal Reserve.

The EBT will give us a detailed listing of every transaction that a client has, and we are also developing retailer profiles. One of the keys to trafficking is the retailer. In some way that coupon has to get back into the Federal Reserve System, and that is through the retailer. With EBT, we are developing profiles on retailers, so that when you have a retailer who does not fit the profile, we can investigate. EBT provides us with a mechanism which we can use to police the redemption system. It gives us a lot more control than the current coupon system. That is one issue.

FOOD STAMP FRAUD IN LOS ANGELES

The second issue is the earthquake in Los Angeles. That was the second disaster that I have had the opportunity to manage or work with. My first experience was in the State of Louisiana with Hurricane Andrew. That experience was one of the primary reasons I went to Los Angeles.

Let me say this up front. The first week in April I have a task force coming in made up of some Federal people and state people to talk about how we can redesign the emergency Food Stamp Program. Some of the problems I saw in California, I saw in Louisiana, and they were also in Florida. We are going to look at that total program. There are some specific things that we think we can do that will reduce the level of fraud.

The key to an emergency Food Stamp Program is how fast you can get food to people whose houses have been demolished and blown away, who have no food, and have been out of electricity for three or four days. It is more of a balancing act because we need the flexibility to react quickly, but we also need to be able to reduce the level of fraud, and that task force will start working in two weeks.

Mr. DURBIN. Tell me what happened in Los Angeles.

Mr. LUDWIG. What part of it specifically?

Mr. DURBIN. Well, I can tell you what I heard, and that was that you were flooded by ineligible people who heard this was the easiest touch in town; that they could come in for emergency food stamps. And when you tried to police it, you had a tough time getting it done.

Mr. LUDWIG. We had to enact some procedures, some delay procedures, because the lines got very long and the county's infrastructure was not designed to handle it.

Mr. DURBIN. I think that may have been a very kind way of saying that you did not get much cooperation from Los Angeles County when it came to police protection, for example, at the site where the food stamp applications were being taken.

Mr. LUDWIG. Let me be cosmetic. [Laughter.]

Mr. DURBIN. Between the cosmic and the cosmetic, I am never going to get an answer today. [Laughter.]

Mr. LUDWIG. We came in after about a week of operation. There were some major problems. So we closed the program for one day to meet with a number of representatives from the Los Angeles area, including the sheriff's department, the fire department, and the police department. We redesigned the emergency Food Stamp Program in one day.

We put in a three-day delay, that would give the County time to do some computer checks on those recipients who were standing in line. That provided some limited control since, in an emergency food stamp situation, many of the people have never been on food stamps, so we do not have a database on them. It gave us time to check on those in line who had been or were currently on food stamps who we would have on a database.

We closed several of the smaller sites because the infrastructure could not handle it so many sites, and opened up what they called super sites—some very large sites with a lot of police. It seemed to go much better after we closed the program and asked the county to look at their infrastructure and reorganize.

Mr. DURBIN. And didn't you do some public service information spots telling people that food stamp fraud was a crime?

Mr. LUDWIG. We actually were handing out brochures as people were standing in line, explaining that food stamp fraud was a crime, what the penalties were if they falsified the information. Those are the same areas we are going to look at with this task force.

We also worked with the Inspector General. I called Washington and talked with him, I think, after the first day I was in Los Angeles. He sent in excess of 40 agents out. I contacted the District Attorney, who provided a great amount of help through the District Attorney's Office. The U.S. Attorney's Office also came into play. It

took a little while to get everybody on board, but once we did things flowed much smoother.

Mr. DURBIN. Thank you.

And after this hearing you can tell me some FEMA stories. [Laughter.]

UNIVERSAL SCHOOL LUNCH AND BREAKFAST PROGRAM

Mr. DURBIN. As you are well aware there are a number of advocates that support a universal type of school lunch and breakfast program. It is believed that this approach would provide a seamless program whereby the school districts wouldn't be bogged down with endless paperwork and could concentrate its efforts on providing all children with nutritious meals. You were required by Senate Resolution 303 to look at a universal school lunch and breakfast program in terms of costs and ways to finance it. At last year's hearing, which took place in March, we were told that a study would be available sometime during the summer. What were the results of your analysis? Please submit a copy of your report for the record.

Mr. LUDWIG. A universal free program implemented in all schools would cost at least an additional \$7 billion at full implementation in 1996 and nearly \$35 billion in additional Federal costs over 5 years. The Fiscal Year 1996 cost represents an increase in excess of 100 percent of current services. Almost half of the cost associated with a universal free system would go to increase payments for meals currently served without improving the nutritional status of the children who are already eating a school meal. In other words, about \$3.4 billion would be spent to raise reimbursement rates for full price and reduced price meals currently served before a single additional meal would be served.

The full report on a universal-type school meals program is currently in Agency clearance. We will provide a copy of this report to the Committee when it is released.

CHILD NUTRITION FUNDING

Mr. DURBIN. The appropriation for child nutrition programs is comprised of two funding levels, appropriated funds and funds transferred from Section 32. The fiscal year 1995 budget request reflects an overall reduction of \$46 million, but the breakout between appropriated funds and funds transferred from section 32 changes significantly. The amount to be derived from appropriations decreases from \$2.73 billion in fiscal year 1994 to \$2.24 billion in fiscal year 1995 while the amount to be transferred from section 32 increases from \$4.77 billion in fiscal year 1994 to \$5.21 billion in fiscal year 1995. What changes have occurred to result in this shift of funds?

Mr. LUDWIG. There is no actual shift in funds. Section 32 is a permanent appropriation equal to 30 percent of the customs receipts collected during the preceding calendar year. After a transfer to the Department of Commerce and an amount is set aside for surplus commodity removal activities, the balance is transferred to the Child Nutrition Programs. The estimate of the 1995 transfer includes \$50 million that, in prior years, was made available for the promotion of sunflower and cottonseed oil exports. If the amount of customs receipts increases significantly, the transfer to

the Child Nutrition account will also increase and the difference between total Child Nutrition funding needs and the Section 32 transfer is the level of new budget authority requested.

The Fiscal Year 1995 appropriation request reflects a decrease because the Food and Nutrition Service will use approximately \$302 million carried over from Fiscal Year 1994 to support reimbursement for anticipated meal service.

Mr. DURBIN. Two reports were issued during fiscal year 1993 concerning child nutrition. One from the Office of the Inspector General titled, Effectiveness of Single Audits, Child Nutrition Programs and one from the General Accounting Office titled, Food Assistance: School Milk Contract Bid-Rigging. Please describe each of these reports. What is the status of each?

Mr. LUDWIG. The Food and Nutrition Service, FNS, was notified by the Department's Office of Finance and Management in February 1994 that final action had been completed for the Office of Inspector General, OIG, Audit Report, "Effectiveness of Single Audits, Child Nutrition Programs", issued in August 1993. The scope of the audit included an evaluation of the use of single audits to identify problem areas in FNS programs. Even though OIG found that corrective action was taken for program deficiencies, they believed that the effectiveness of single audit reports was limited because neither FNS nor State agency managers performed a formal trend analysis of findings to determine whether further monitoring and/or guidance was needed. To respond to the audit recommendations FNS regional offices were advised to notify State agencies of the importance of single audits as a management tool for assessing controls over Federal assistance to State agencies and local school districts as well as in determining trends and problems common to more than one school district. Additionally, a review of the monitoring of single audits is required for all regional office reviews of State agencies conducted in Fiscal Year 1994. However, FNS wishes to stress that all audit findings are considered in National program evaluations and have been reflected in a number of program integrity initiatives.

The General Accounting Office, GAO, published its final report entitled Food Assistance: School Milk Contract Bid-Rigging, GAO/RCED-93-5, on October 16, 1992. The report was issued in response to a request submitted by Congressman Tom Coleman for an examination of bid-rigging on school milk contracts to determine if problems exist with respect to agricultural laws or their administration which may allow bid-rigging to occur. Subsequent to the publication of the Report, FNS has implemented several actions to enhance the Agency's capabilities to deter bid-rigging in relation to FNS programs as well as to aggressively enforce the Department's nonprocurement debarment and suspension regulations, when warranted, to protect the public interest. Such initiatives include: the creation of a dedicated task force assigned to work exclusively on suspension and/or debarment actions against any company or individual found guilty of bid-rigging or other serious offenses; the assignment of an attorney from the Office of the General Counsel to handle FNS suspension and debarment issues; increased training sessions for State and local school procurement officials focusing on procurement and the potential for bid-rigging; increased efforts to

formalize and streamline channels of communication between the Department of Justice and the Office of the General Counsel; and increased efforts to improve sharing of information between FNS and other agencies.

On January 3, 1994, FNS was contacted by GAO's Kansas City Regional Office and advised that GAO would be conducting a follow-up examination of FNS actions undertaken since the October 16, 1992 publication of the report. Recently, GAO representatives met with Child Nutrition Division program staff to review case files and recent initiatives undertaken by FNS in response to the October GAO Report. While the scope of the follow-up examination went beyond a review of dairy bid-rigging to include an examination of violations relating to other commodities used in FNS programs, the major focus was on the steps taken by FNS to develop a systematic process for initiating suspension and debarment actions. The results of this review have not yet been forwarded to FNS.

SCHOOL LUNCH BUDGET REQUEST

Mr. DURBIN. Help me understand your request for the School Lunch program. You project an increase in the number of meals to be served in all three categories, you project an increase in the meal reimbursement rate, and you expect an increase in average participation, yet you are requesting a decrease in the appropriation level. Please explain the reason for this.

Mr. LUDWIG. The appropriation for Child Nutrition Programs provides for two year spending authority. It is estimated that approximately \$302 million of the Fiscal Year 1994 appropriation will be available at the close of the fiscal year for use in Fiscal Year 1995. The Fiscal Year 1994 carryover funds plus the appropriation request for Fiscal Year 1995 will support full reimbursement for meal service currently projected for Fiscal Year 1995.

SCHOOL BREAKFAST PROGRAM

Mr. DURBIN. For the school breakfast program you project the number of meals served to increase by 51 million. Of this increase, 42 million is expected to be in the below 130 percent of poverty category. Why is there such a significantly higher increase in this category?

Mr. LUDWIG. The meal projections for the School Breakfast Program are based on current trends in breakfast service. Due to a variety of factors, the School Breakfast Program continues to grow at a rapid pace—in 1994, 5,400 additional schools added the program. However, even as more schools participate in the program, over 82 percent of the children who participate are from low-income families. The ratio of free and reduced priced meals to total meals has not changed significantly since the early 1970's.

Mr. DURBIN. In fiscal year 1993, school breakfasts were available to approximately 26.5 million children daily, yet the average number of children eating breakfasts daily was about 5.5 million. Why aren't more children taking advantage of the school breakfast program?

Mr. LUDWIG. The School Breakfast Program (SBP) is one of the fastest growing Child Nutrition Programs. Since 1990, the Food

and Nutrition Service has awarded \$23 million in start-up funds to make the SBP available to new school districts. The Program has grown from \$3.5 million in 1986 to its current level of \$5.9 million in Fiscal year 1994; an increase of about 57 percent. We anticipate further growth based on continuing outreach efforts.

Schools have many factors to consider in deciding whether to offer a breakfast program including whether or not a school is needy, whether a school is large enough to support a program, whether bus schedules will coincide with the serving of school breakfast, whether teachers are available to staff the cafeteria, and whether kitchen facilities are adequate for preparation. There are also many reasons children do not participate when the Program is available. They have other options for breakfast, such as eating at home, stopping off at the neighborhood store, or eating at a fast food establishment.

Nevertheless, we are proud of our success in expanding the program and we believe that as more and more schools offer the program and more and more families come to realize what a good value the school breakfast is, we will see even more dramatic growth in participation rates.

Mr. DURBIN. How many schools are providing a school lunch program? How many of these schools are also providing a school breakfast program? How does this compare to the total number of schools providing a breakfast program?

Mr. LUDWIG. This year over 93,000 schools are providing a School Lunch Program. Of those, 60,500 or about 65 percent are also providing a school breakfast program. There are very few schools that serve breakfasts which are not part of the United States Department of Agriculture, USDA, School Breakfast Program. A recent study showed that less than 1 percent of schools offer a program identified by the principal as breakfast service that is not part of the USDA program.

Mr. DURBIN. Please update the table that appears on page 212 of last year's hearing record showing the number of meals that were served, by category, in the school breakfast program to include fiscal year 1993.

Mr. LUDWIG. The information requested will be submitted for the record.

[The information follows:]

SCHOOL BREAKFAST PROGRAM MEALS SERVED BY CATEGORY

[Thousand meals]

	Fiscal year—					
	1988	1989	1990	1991	1992	1993
Paid	80,538	86,603	94,036	97,795	102,548	112,325
Free-reg	222,224	224,988	227,481	237,067	259,144	269,819
Free-sn	309,237	314,000	348,853	394,510	447,188	493,653
Sub free	531,461	538,988	576,334	631,577	706,332	763,472
Red-reg	14,821	15,975	18,474	21,473	21,431	22,488
Red-sn	15,713	16,889	18,681	21,365	22,222	24,887

SCHOOL BREAKFAST PROGRAM MEALS SERVED BY CATEGORY—Continued

[Thousand meals]

	Fiscal year—					
	1988	1989	1990	1991	1992	1993
Sub reduced	30,534	32,864	37,155	42,838	43,653	47,375
Total	642,533	658,455	707,525	772,210	852,533	923,172

SUMMER FOOD SERVICE PROGRAM

Mr. DURBIN. In the summer of 1993, approximately 109 million meals were served in the Summer Food Service program at an estimated cost of \$228 million. This averages out to be a little over \$2.00 per meal. How does this rate compare to other child nutrition programs?

Mr. LUDWIG. The average reimbursement for the Summer Food Service Program, SFSP, is higher than the average rate for other child nutrition programs. In the SFSP, the breakfast, lunch and supplement operating cost reimbursement rates are \$1.16, \$2.0825 and \$.5450, respectively. The administrative cost reimbursement rates are \$.1075 for breakfast, \$.1975 for lunch and \$.0525 for supplements. Sites located in rural areas or those sponsors who prepare their own meals receive a slightly higher rate.

The SFSP reimbursement rates are higher for several reasons. First, both the sites and sponsors in the SFSP are smaller than the institutions managing other child nutrition programs such as the National School Lunch Program. As a result, the sponsors and sites are unable to reduce their costs by purchasing large quantities of commodities. In addition, in many summer sites, food must be transported to the program since kitchens are not available at the site. Furthermore, day-to-day participation in SFSP is less predictable than school programs, which means providers must often over produce meals to ensure that all who may attend a site on any given day can be served. This, in turn, increases total per meal costs relative to other programs.

Mr. DURBIN. At last year's hearing, Mr. Braley told the Committee the Department was in the process of analyzing data collected during the 1992 reviews of all private non-profit sponsors in the summer food service program. What were your findings and recommendations of this analysis?

Mr. LUDWIG. The analysis of the 1992 reviews found that approximately 300 private nonprofit organizations operated 850 sites serving 70,000 children a day. Over half of the private nonprofit sites were located in rural areas. The analysis also found that although administrative and operational problems still exist, the magnitude of the problems have decreased since 1991. For example, from 1991 to 1992 the percent of private nonprofit sponsors that had meals disallowed decreased from 21 percent to 15 percent. However, one recurring problem is that reviewers found the number of meals served on the day of the review was less than the average number of meals served the previous five days. This may indicate that we still have a problem with over claiming.

CHILD AND ADULT CARE FOOD PROGRAM

Mr. DURBIN. In the Child and Adult Care Food Program, non-profit child care centers and family and group day care homes receive subsidies for meals served to preschool and other children. Meals served to children in centers are means tested with higher subsidies going to meals served to low income children. Meals served in day care homes are not means tested with the higher free reimbursement rate going to all meals served. Why is there a difference in the way the program is administered in day care centers and day care homes?

Mr. LUDWIG. Originally, the Child and Adult Care Food Program, CACFP, was designed to help child care providers with nutrition assistance to children in low-income areas or in areas in which there was a large concentration of working mothers. Prior to 1978, participating child care centers and child care homes both served primarily needy children and meals were reimbursed at rates which varied according to the income category of the family of the child served, with the neediest children receiving free meals. This structure ensured a higher Federal subsidy for a meal served to a child from a family with low income and continues to exist in centers today.

To better help the needy by bringing more family day care homes, FDCH, onto the program and to recognize the administrative burden placed on homes, Congress simplified this reimbursement structure and reduced paperwork for homes in 1978 by authorizing a single meal reimbursement factor at a rate set by the Secretary such that income applications were not needed. Since nearly all children in program homes were from low income households eligible for free meals in 1978, the FDCH reimbursement factor was set by the Secretary at the "free" rate. Since 1978, with the exception of meals served to children of the providers themselves, all meals have been served free in family day care homes.

We are concerned that today 71 percent of the children in program homes are from non-needy families. Thus, the program has shifted from simplifying the rate structure to help the needy, to helping the non-needy with a disproportionate amount of subsidies. Only 16 percent of FDCH households have incomes at or below 130 percent of poverty. Furthermore, since 1978 family day care home reimbursements have grown from \$12.6 million, about 8 percent of the total CACFP costs, to approximately \$723 million, or about 59 percent of total program costs. Meanwhile, children receiving meals through Child Care Centers receive subsidies based on need.

Mr. DURBIN. For the child and adult care food program in day care centers you project the number of meals served to increase by 107 million. Like the school breakfast program the majority of this increase, 80 million, is expected to be in the below 130 percent of poverty category. Why is there such a significantly higher increase in this category?

Mr. LUDWIG. The increase in the below 130 percent of poverty category (the "free" category) represents about 75 percent of the increase. Free meals make up the majority of all meals served in centers, about 62 percent in 1993. Thus the majority of new center meals would also be expected to fall into the free category. In addi-

tion, the meal projections for 1995 and beyond explicitly account for projected major growth in the Head Start program, which would result in increases in the number of free meals served in the centers.

Mr. DURBIN. Under the provisions of Section 32, the Secretary can use funds for emergency surplus removal purchases and donate these commodities to schools and institutions. Were there any emergency surplus removal commodities donated to the schools during fiscal years 1992, 1993, and so far in 1994?

Mr. LUDWIG. Section 32 funds allow the Secretary to make emergency surplus removal purchases and donate them to schools and other institutions. Typically, the commodities include fruits and vegetables.

During Fiscal Year 1992, 1993, and 1994 the United States Department of Agriculture purchased \$38.8, \$64.0, and \$32 million worth of commodities, respectively. A chart detailing these purchases by commodity will be submitted for the record.

[The information follows:]

LIST OF SEC-32 TYPE BONUS FOODS PROVIDED TO SCHOOLS

SECTION 32-TYPE COMMODITIES (GROUP A) BONUS	SY 1992 SCHOOLS TOTAL POUNDS	SY 1992 SCHOOLS TOTAL VALUE	SY 1993 SCHOOLS TOTAL POUNDS	SY 1993 SCHOOLS TOTAL VALUE	SY 1994 SCHOOLS TOTAL POUNDS	SY 1994 SCHOOLS TOTAL VALUE
POTATO, BAKING			1,436,250	\$234,880		
BEANS, VEGETARIAN			5,202,022	\$1,577,226		
BEANS, REFRIED CND			1,689,072	\$532,792		
ASPARAGUS, FROZEN	80,040	\$100,162	185,940	\$244,821		
ASPARAGUS, CANNED	952,496	\$857,225	577,216	\$359,358		
POTATO, FRESH			8,664,596	\$4,331,328		
POTATO, GRANULES						
SHEET POTATOES, STRUP						
SHEET POTATOES, MASHED						
TOMATOES, CRUSHED	4,909,284	\$1,549,858	6,849,618	\$2,071,438	4,125,387	\$1,762,333
TOMATOES, FRESH			9,009,018	\$2,401,920	224,352	\$100,888
TOMATO PASTE, CANNED	2,471,308	\$956,647	4,598,057	\$1,707,730		
TOMATO SAUCE, CANNED			7,042,534	\$1,802,203		
TOMATOES, CANNED	3,431,181	\$1,026,266	3,945,458	\$1,303,038		
ALMONDS, BUTTERS	5,668,345	\$6,611,556	1,219,375	\$2,363,497		
APPLES, FRESH						
WALNUTS, ENGLISH PIECES	1,420,800	\$2,313,634			273,698	\$59,269
GRAPEFRUIT			771,283	\$127,073	216,810	\$31,824
ORANGE JUICE, CND			8,238,096	\$2,786,206	10,418,580	\$5,304,379
ORANGES					15,901,690	\$7,327,445
CHERRIES, FRZ			468,332	\$82,525		
RASPBERRIES, FROZEN	99,706	\$84,072	8,977,890	\$3,892,315		
BLACKBERRY, EVERGREEN PUREE			2,528,100	\$1,459,612		
BLACKBERRY, MARION PUREE			690,897	\$470,026		
BLUEBERRY, FRZ, WILD			674,958	\$586,667		
PEACHES, FRESH						
PEACHES, CND						
PEACHES, FRZ						
PEARS, HALVES						
PEARS, SLICED						
PEARS, FRESH						
PEARS, FRESH D'ANJOU						
PEARS, FRESH BOSC						
MIXED FRUIT						
DATE, PIECES	1,510,350	\$895,409	4,547,720	\$3,021,959		
RAISINS, SEEDS	3,722,310	\$1,897,719	3,899,287	\$1,641,363		
RAISINS, SOFT	5,925,360	\$3,158,401	4,848,753	\$2,000,921		
CHICKENS, FRZ DRUMSTICKS						
CHICKEN, LEG QUARTERS			1,884,760	\$651,788		
CHICKEN, COZZETTIGS			2,486,360	\$773,631		
CHICKEN, COZZETTIGS, PACK			826,400	\$304,627		
TURKEY, CANNED W/J						
PORK, CANNED	17,648,550	\$10,359,931	7,911,490	\$10,059,381		
WAL, FRZ COOKED BONELESS	4,326,670	\$5,545,887	7,465,964	\$11,757,662		
CATFISH, FRESH						
WAL, FRZ COOKED BONELESS						
CATFISH, FRESH	252,000	\$733,320				
WAL, FRZ COOKED BONELESS	1,764,967	\$2,950,517				
SALMON, PINK CANNED			2,251,445	\$3,652,465	4,091,552	\$6,112,925
BEANS, DRY PINTO			3,477,257	\$750,446		
BEANS, DRY						
TOTAL GROUP A BONUS	52,513,873	\$38,834,017	111,691,892	\$43,952,711	56,887,534	\$32,013,795

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COMMODITY PROCUREMENT

Mr. DURBIN. The appropriation for commodity procurement is proposed to increase by a net amount of \$20.4 million. Included in this amount is a \$21 million increase in Federal entitlement commodity support as required by law. Would you please describe this requirement in further detail?

Mr. LUDWIG. Section 6(e) of the National School Lunch Act of 1946, as amended, establishes the national average value of donated food assistance to be given to States for each lunch served in the National School Lunch Program, NSLP, at 11.00 cents, subject to annual adjustment to reflect changes in the Price Index for food Used in Schools and Institutions. Section 17(h)(1) of the Act requires that the same value of assistance in donated foods for NSLP also be provided for lunches and suppers served in the Child and Adult Care Food Program, CACFP. For school years 1992-1994, the required per-meal commodity support has remained constant at 14.00 cents.

The \$21 million increase in Federal entitlement commodity support for Fiscal Year 1995 is based on: a projected increase in the number of meals served through NSLP and CACFP, a projected increase in the required per-meal commodity support, from 14.00 cents to 14.25 cents, and commodity administrative costs, which are estimated to increase from \$5.9 million in Fiscal Year 1994 to \$7.2 million in Fiscal Year 1995.

Mr. DURBIN. The explanatory notes state that the commodity procurement budget request reflects a change in the projected commodity reimbursement rate based on a forecast of the Producer Price Index. Please explain this change in further detail.

Mr. LUDWIG. Each July 1, the reimbursement rate for commodities to the Child Nutrition Program is adjusted to reflect changes in the Producer Price Index for Foods Used in Schools, PPI. This series is a weighted composite of five PPI series averaged for March, April, and May and is compiled and projected by the Economic Research Service of the United States Department of Agriculture USDA, for Food and Nutrition Service, FNS. The series is lagged one year and the percent change in the PPI Series from the base year, Fiscal Year 1982, is computed. Commodity reimbursement rates are then adjusted by multiplying the "commodity rate" in the base period by the "percent", and rounding to the nearest one quarter percent.

The Fiscal Year 1995 estimated commodity reimbursement rate reflects the projected increase in the PPI Series.

COORDINATED REVIEW EFFORT

Mr. DURBIN. State training and transition activities for the Coordinated Review Effort occurred during the first quarter of fiscal year 1993 with actual reviews beginning in the second quarter. Data for school year 1993 will be available this month. Give us a preliminary assessment of how the system is working? Is it achieving the goals as intended; what are its strong points as well as its weak points; are any changes needed in the way it's being carried out; are States in compliance; is a review once every four years enough; now that it's operational are States more accepting of it?

Mr. LUDWIG. The Coordinated Review Effort, CRE, affords State agencies the flexibility to establish review schedules based on available resources with the stipulation that all school food authorities would be reviewed within the first 4-year review cycle ending June 30, 1997. However, we have begun receiving State agency summary data for the first year of CRE. These State agency summary reports are preliminary and the data is unverified. Based on the preliminary information received from 14 States, payments have been withheld by five State agencies for school food authority failure to correct accountability deficiencies following Coordinated Reviews. When all of the reports are received and the analysis of the data is completed, it will provide a good indicator of the results of CRE for most State agencies. However, since not all State agencies will be reporting data based on a full year of CRE, due to delayed implementation permitted by the regulations, conclusions on a National basis will not be available for the first year of this review cycle.

We have recently been advised by the Office of Inspector General (OIG) that they will be conducting a Nationwide audit of meal accountability in the National School Lunch Program. One of the audit objectives is to evaluate the effectiveness of administrative reviews both in terms of identifying problems and oversight of corrective action. The Midwest, Northeast and Western regions have been selected and field work is to begin this month. An audit report will be used for each regional office. OIG anticipates that draft audit reports will be available by July 31, 1994. OIG will then issue a rollup audit report to the Food and Nutrition Service, FNS, based on the final reports issued.

In recent months, local and State objections to the system have subsided although several State Directors continued to raise objections during the recent American School Food Service Association legislative conference. FNS continues to be responsive to concerns raised.

Mr. DURBIN. Although there is no change in the amount being requested for the Coordinated Review Effort, there is a net increase of \$161,000 being requested in the funding level for school operations. How much of the fiscal year 1994 appropriation is available for school operations? What is this funding used for? What is the increase being requested for?

Mr. LUDWIG. The Coordinated Review Effort is a system in which Federal personnel along with State and local agencies conduct management evaluations and provide technical assistance to improve program operations at schools. The appropriation of \$3.849 million supports these activities. The additional \$161,000 is the increase associated with inflation and is not associated with pay costs.

DIETARY GUIDELINES

Mr. DURBIN. You are requesting an increase of \$18,443,000 for dietary guidelines. Of this amount, \$8,443,000 will be used to implement the dietary guidelines. The explanatory notes state this increase will be used to provide Federal and State technical training and assistance, meal pattern analysis and assessment, menu planning technical aids, recipe development, computer equipment sup-

port to school districts, and incentives for school districts to meet the dietary guidelines. Would you please provide a breakout of how the \$2,054,000 appropriated in fiscal year 1994 is being spent as well as a breakout of how the proposed increase of \$8,443,000 will be spent?

Mr. LUDWIG. To date, we have committed approximately \$313,000 in Fiscal Year 1994 appropriations in support of a number of activities. I will provide a breakout for the record.

The remaining \$1.7 million in Fiscal Year 1994 funds will be spent on a national nutrition education media campaign which is in the very early stages of conception and development.

As for the \$8.4 million request for Fiscal Year 1995, we will make grants to the States which are targeted for training and technical assistance to enable them to implement the Dietary Guidelines into the Child Nutrition Programs. Activities will include training in nutrient analysis and healthy menu planning, low-fat recipe development and food preparation, nutrition training for class room and food service staff emphasizing the food-health connection and chefs-in-the-schools partnerships.

[The information follows:]

Dietary guidelines commitments to date

Field hearings on Implementing the Dietary Guidelines into the Child Nutrition Programs	\$94,000
Implementation of NET Program National Needs Assessment Guidelines	43,000
Implementation of new Child Care Program recipes	140,000
Dietary Guidelines Publication for Spanish speaking participants	25,000
Miscellaneous expenses (publications storage, handling, mailing, etc.)	11,000

Mr. DURBIN. Describe in further detail the proposal to provide computer equipment support to school districts for implementing the dietary guidelines.

Mr. LUDWIG. The Department is developing a specialized database to support accurate nutritional analysis of the goods being served in schools. The Department also designed the specifications for the software schools will use to analyze their menus for compliance with the Dietary Guidelines. Both the database and the software specifications are available without charge to schools, food manufacturers and the software industry. USDA will also train all State-level school food service personnel in the use of this database and software. In addition, the Department will provide grants to States in Fiscal Year 1995 to enable States to train local food service personnel in the use of the new database and nutrient analysis software. The Department is still refining its policy proposal to permit States to facilitate computer hardware and software purchases by financially hard-pressed school districts.

Mr. DURBIN. Also describe in further detail the proposal to provide incentives for school districts to meet these guidelines.

Mr. LUDWIG. We are still in the process of making final decisions on the issues that are involved in our initiative to improve school meals for the Nation's children. We are considering various technical assistance and training programs, however, it would be premature to discuss any details. We are clearly taking direction from the President's framework for reinventing government and also taking advantage of input we have received from individuals and organizations through the public hearing process. In that light, we

are making every effort to ensure that our proposals are consistent with the concepts of streamlining administration, providing flexibility and empowering the food service professionals who work with these programs.

These incentives are contained in proposed rulemaking which is currently in clearance. We are hoping to publish the rule within the next month or so. We do not believe it appropriate to speculate on the contents of the regulation until it has completed its clearance of the Office of the General Council and the Office of Management and Budget.

FOOD SERVICE MANAGEMENT INSTITUTE

Mr. DURBIN. The Food Service Management Institute was established to provide technical assistance and training to school food service personnel on nutrition and improving the dietary status of meals served to children in schools. How is what you are proposing to do different than the mission of the Institute?

Mr. LUDWIG. There is an on-going cooperative effort between The Food and Nutrition Service, FNS, and the National Food Service Management Institute. We look to the Institute to complement and enhance our efforts in the mission to improve school meals as negotiated in the annual work plan. This year we have asked the Institute to specifically conduct research on the equipment needed in schools to prepare and serve foods to meet dietary recommendations. Currently, we are asking the Institute to provide a useful tool for school managers on procurement to ensure that purchasing practices are in line with the Dietary Guidelines. We continue to look to the Institute's expertise in school food service training, providing technical assistance on feeding children with special needs and the promotion of healthy food practices through their satellite distance learning programs. As the Department's initiative progresses, we will continue to collaborate with and involve the Institute.

DIETARY GUIDELINES

Mr. DURBIN. It is stated in the explanatory notes that increased technical assistance is necessary for school districts to implement the dietary guidelines in food service by 1998. Is this a requirement that is mandated by law or regulation?

Mr. LUDWIG. The Food and Nutrition Service needs to provide substantial technical assistance to States and schools as they transition to nutrient standard meal planning from meal pattern menu planning. The law mandates that meals served under the National School Lunch Program meet minimum nutritional requirements prescribed by the Secretary on the basis of tested nutritional research. Our goal is to offer children meals that comply with the Dietary Guidelines for Americans. We are currently working on a number of initiatives to improve children's diets and assist schools in implementing the Dietary Guidelines through nutrient standard menu planning.

The School Nutrition Dietary Assessment study, released last fall, found that while the current lunch pattern provides many important vitamins and nutrients, on average, lunches exceed the Dietary Guidelines for Americans for fat and saturated fat, and are

high in sodium. Our basic approach to providing nutritional guidance has not been updated or changed since the program began in 1946.

We believe that nutrition education and technical assistance to school districts is necessary based on numerous discussions with and comments received from school food service professionals. Many changes must be made. For example, recipes need modification, and food service staff need to learn new preparation and procurement techniques for new foods. This shift in practices is not a trivial exercise for the 92,000 schools and thousands of professionals that prepare the 25 million lunches served daily through the National School Lunch Program.

In short, we believe that this investment in technical assistance is essential to achieving the health and nutrition potential of school meals. I see this initiative as a way to leverage our current \$4 billion investment in school meals into an investment in the future health of our nation's citizens.

Mr. DURBIN. The remaining requested increase of \$10,000,000 will be used to develop national nutrition education programs for pre-school and school-age children. The Nutrition Education and Training Program, NET, which has been operating since 1977, provides funds to state agencies for the development of nutrition education and information programs. How will the Department's proposal be different than the NET program?

Mr. LUDWIG. The National Education and Training (NET) Program emphasizes an independent assessment of the nutrition education and training needs in each State and the use of that State's NET grant to address those needs. The Department's nutrition education and communication's proposal emphasizes a national focus to implement the Dietary Guidelines into the school nutrition programs by 1998. This centralized effort capitalizes on economies of scale and thematic consistency in developing a consumer-based comprehensive nutrition education effort to provide leadership and direction change. The campaign will produce educational products and services that all the States can use and incorporate into their own individual efforts. These two approaches do not compete with each other; they complement and reinforce one another.

Mr. DURBIN. Why do we need to continue funding all three programs, the Food Service Management Institute, the NET Program, and the Dietary Guidelines? What benefits or services does one program provide that another is not or cannot provide?

Mr. LUDWIG. We need all three programs because each has a different mission and focus. The Food Service Management Institute provides training and technical assistance to food service personnel in order to improve the quality of meal service. The Nutrition Education Training Program provides nutrition education for children and teachers in schools, day care centers and homes, and provides nutrition education curricula and materials to help teachers, parents and food service staff teach children the relationship between food and health in the classroom, the cafeteria and the home. The Department's Dietary Guidelines implementation campaign has two parts: a national education and communications effort aimed at improving the health of America's children by improving their diets and guidance and support to the States in the form of grants

for training, as well as technical assistance materials such as menu planning guides, new recipes, training manuals, and food service resources.

RECIPE DEVELOPMENT

Mr. DURBIN. At last year's hearing, the Committee was told that FNS was working with the Department of Defense on an inter-agency agreement for recipe file development and standardization. What is the status of this agreement? Why was this being negotiated with DOD?

Mr. LUDWIG. The discussions with the U.S. Army Natick Research Center were begun in February, 1993 because of their continuing celebrated reputation for quality recipe development for the military. Negotiations with Natick regarding development of 50+ new recipes for the National School Lunch and Breakfast Programs continued from February 2, 1993 until the middle of March, 1993.

Negotiations concerning the project were terminated at that time because the prospective Principal Investigator, Ms. Pat Prell, announced her retirement. This elicited doubts as to whether the project could begin within the USDA Food and Nutrition Service September timeframe.

Consequently, Requests for Applications were submitted to eight land-grant universities within a 250-mile radius of the Food and Nutrition Service in Alexandria, Virginia, resulting in an award to The Pennsylvania State University on September 10, 1993. We are now in the sixth month of that contract, which will be completed in August. Arrangements for publication of the new recipes will commence in September, for dissemination to all schools in the Spring of 1995.

NUTRIENT STANDARD MENU PLANNING

Mr. DURBIN. Last year you planned to introduce an alternative method to the current meal pattern for implementing the dietary guidelines. The new method, called nutrient standard menu planning, would require school meals to meet a specific nutritional standard rather than a food-based meal pattern. Has this alternative been introduced? Has it been tested? If so, what were the results?

Mr. LUDWIG. The nutrient standard menu planning demonstration project is underway. The demonstration, which will span three years, begins in schools this Fall. Within the last few months, 35 school districts from across the country were chosen to participate. Care was taken to select districts of varying enrollment sizes, from a variety of geographic areas, representing a wide range of experiences with nutritional analysis of meals. This is important for understanding the effects of nutrient standard menu planning in all types of school districts.

The Food and Nutrition Service will provide training for States and these school sites in June. An independent evaluation of the demonstration will be conducted, with baseline data collection scheduled for this Spring. The first year of the evaluation will examine the processes used by the school districts, problems encountered and solutions devised, with a report scheduled for late Summer 1995. The second evaluation year will measure dietary impacts

from this new method of menu planning, with a report scheduled for early 1997.

BEEF PATTIES

Mr. DURBIN. Please update the table that appears on page 217 of last year's hearing record showing the amount of beef patties that were delivered to school districts to include school year 1994.

Mr. LUDWIG. I will provide an updated table showing the amount of beef patties that were delivered to school districts which includes amounts purchased in School Year 1994.

[The information follows:]

BEEF PATTIES DELIVERED FOR SCHOOL YEAR 1992, 1993 AND 1994

			Beef patties—		
			100 percent	VPP	Lean
SY 1992	Pounds		9,228,528	22,048,452	3,737,880
	Dollars		12,671,407	25,049,082	6,628,768
SY 1993	Pounds		9,131,580	20,747,376	6,766,766
	Dollars		12,284,616	23,085,112	10,729,386
SY 1994	Pounds		4,960,872	18,995,436	5,497,056
	Dollars		6,780,307	20,669,591	8,832,533

¹ Vegetable protein products.

LOW-FAT PRODUCTS IN CNP

Mr. DURBIN. Other than low-fat patties, have there been other low-fat products developed and tested in meals served to children through the child nutrition programs?

Mr. LUDWIG. Developing and testing low-fat products is a top priority and an on-going effort. For example, during the past school year we have introduced turkey sausage and low-fat salad dressing and low-fat cheddar cheese. We plan to test a low-fat mozzarella cheese next school year. In addition to introducing low-fat items, we have doubled our purchases of fresh fruits and vegetables. We are currently monitoring test purchases of fresh corn and fresh carrots.

PAPERWORK REDUCTION PILOT PROJECTS

Mr. DURBIN. The Department is testing three types of alternative meal counting and claiming pilot projects in ten sites around the country. These included: tests of extended application intervals; tests of providing meals at no charge to all students; and tests of direct certification. What is the status of these pilots? What are the findings and recommendations of each?

Mr. LUDWIG. The Paperwork Reduction Pilot Projects were originally authorized to operate through this school year. Recently, the Department authorized a 1-year extension for those districts that wish to continue the procedures that they have been using under the pilot provisions. This will provide the Department and Congress time to examine the results of the evaluation and avoid any disruption that might occur if the projects were terminated and Congress subsequently extended them as part of reauthorization.

An interim report detailing results from the first year of pilot operations is currently in Agency clearance. We will provide the Com-

mittee with a copy of the interim report when it is released. A final report including results from all three years will be available in the fall.

FNS OPERATED PROGRAMS

Mr. DURBIN. Of the \$94 million proposed for State administrative expenses, approximately \$500,000 will be used by FNS to administer child nutrition programs in seven States. For the record, please list the programs that you directly operate as well as the States where the programs are located.

Mr. LUDWIG. I will provide a chart of the child nutrition programs which are directly administered by the Food and Nutrition Service for the record. For your information there are two Federal sources of State administrative funding for the administration of the child nutrition programs. State Administrative Expense funds are used to administer the National School Lunch Program, School Breakfast Program, Special Milk Program and Child and Adult Care Food Program. A separate source, State Administrative Funds are used to administer the Summer Food Service Program.

[The information follows:]

CHILD NUTRITION PROGRAMS DIRECTLY ADMINISTERED BY THE FOOD AND NUTRITION SERVICE

New York	SFSP.
Delaware	NSLP, SBP, SMP—private schools.
Virginia	CACFP.
	SFSP.
	NSLP, SBP, SMP—private schools, private RCCIs.
	SMP—summer camps, non-RCCIs.
Georgia	NSLP, SBP, SMP—private RCCIs.
	SMP—summer camps, non-RCCIs.
	SFSP.
South Carolina	NSLP, SBP, SMP—private schools, public and private RCCIs.
	SMP—summer camps and non-RCCIs.
Michigan	SFSP.
Colorado	NSLP, SBP, SMP—private schools, private RCCIs.
	SMP—non-RCCIs.
Missouri	NSLP, SBP, SMP—public and private RCCIs.
	SMP—summer camps, non-RCCIs.
California	SFSP.

Key: National School Lunch Program—NSLP; School Breakfast Program—SBP; Special Milk Program—SMP; Child and Adult Care Food Program—CACFP; Summer Food Service Program—SFSP; and Residential Child Care Institution—RCCI.

STATE ADMINISTRATIVE CARRYOVER FUNDS

Mr. DURBIN. A State is allowed to carryover up to 20 percent of its administrative funds from one fiscal year into the next. Provide a table showing the amount of State administrative expenses that have been carried over and what percent it was of the total appropriation for each of the fiscal years 1989 through 1994.

Mr. LUDWIG. A table showing the amount of State administrative expenses that have been carried over and the percent it was of the total allocation to State agencies for Fiscal Years 1989 through 1993, will be submitted for the record. Appropriated State administrative expenses are allocated to the State agencies and to the Food and Nutrition Service for the programs it administers directly. The

carryover provision applies to only the State agencies. Therefore, the table reflects only funds allocated to, and subsequently carried over by, State agencies. Data is not yet available for Fiscal Year 1994.

[The information follows:]

STATE ADMINISTRATIVE EXPENSE FUNDS CARRYOVER HISTORY

[In millions]

Fiscal year	Amount carried over	Amount of original allocation	Percent of allocation carried over
1993 ¹	12.5	76.2	16.4
1992	11.6	67.2	17.3
1991	15.3	61.3	25.0
1990	21.1	58.5	36.1
1989	22.2	55.4	40.1

¹ Please note that this data is preliminary.

CNP STUDIES

Mr. DURBIN. Two studies were performed during fiscal year 1993. One was a study to determine the actual costs to produce a school lunch and breakfast, and the other was a study to evaluate the effects a multi-use school lunch application had on lunch participation rates. What were the results of each of these?

Mr. LUDWIG. These two studies are not yet completed. Data collection for the School Lunch and Breakfast Cost Study occurred in the Spring and Fall of 1993 and is currently being analyzed. A draft report for the Evaluation of the West Virginia Multi-use Application is currently being reviewed by the Agency. These two reports are scheduled to be released early this summer. We will gladly provide the committee with a copy of these reports when they are released.

CHILD AND ADULT CARE FOOD PROGRAM

Mr. DURBIN. During fiscal year 1994, the State of New York assumed operations of the Child and Adult Care Food program. The Federal staff years that were assigned to this work were reassigned to other work. Tell us how many staff years this involved and what work they are now performing.

Mr. LUDWIG. A total of 12 staff-years were assigned to the Regional Office Administered Program, ROAP, in New York. In support of the President's Executive Order mandating a reduction of 252,000 Federal positions by Fiscal Year 1998, the agency reduced the above staff-years by 5. Two of the five staff-year reductions resulted from employment termination and, subsequently, the vacancies were not filled.

A number of staffing changes have taken place with the remaining 7 staff years. Four staff were used to fill vacancies in the Special Supplemental Food Program for Women, Infants, and Children, WIC, operations, Child Nutrition program operations, Wallingford Field Office, and the New York City Field Office, the staff is also involved in Food Stamp Quality Control and Retail/Wholesale work. Three are performing ROAP transition functions, including State agency oversight, technical assistance and training. Also,

ROAP Summer Feeding program activities are still in operation in New York.

BONUS COMMODITY DONATIONS

Mr. DURBIN. It was reported by school food authorities that reductions in the level of bonus commodity donations affected their food service operations. Specifically how have these reductions affected their operations?

Mr. LUDWIG. The amount of bonus commodities distributed to schools peaked at \$440 million in 1987. However, since its peak in 1987, the amount of bonus commodities distributed has dropped considerably. In 1992, the Department distributed \$86 million worth of bonus commodities to schools.

In the report, Child Nutrition Program Operation Study: Third Year, school food authority managers were asked about the perceived impact of the decrease in bonus commodities. When asked to list specific effects, most managers noted that they changed their menus. The report also found that managers had increased their total food costs, used more convenience items and/or increase meal prices. Although the loss of bonus commodities has had some impact on the schools, the extent of that effect on operations is unknown.

HOMELESS DEMONSTRATION PROJECT

Mr. DURBIN. A child nutrition homeless demonstration project was authorized and conducted during fiscal years 1993 and 1994. The funding for this project came from State administrative expenses. Would you provide the Committee with a description of the project, the amount spent in each fiscal year, the number of children served, and an analysis of the results of the project.

Mr. LUDWIG. P.L. 101-147 authorized \$350,000 for the Child Nutrition Demonstration Project in each of the Fiscal years 1991 through 1994 and allowed, depending on availability, recovered State Administrative Expense, SAE, funds to be used for the demonstration. The Child Nutrition Improvement act of 1992, P.L. 102-342, increased the authorization to \$650,000 for Fiscal Year 1993 and to \$800,000 for Fiscal Year 1994, and specified that up to \$4 million in recovered SAE funds may be used in each of Fiscal Years 1993 and 1994.

The purpose of the demonstration project is to determine the best means of providing food assistance to homeless preschool children in shelters. The demonstration projects provide regularly scheduled food service throughout the year to homeless children under the age of 6 in emergency family shelters. Sites must meet applicable State and local health, safety, and sanitation standards. With this project the Child and Adult Care Food Program meal patterns are used and the same reimbursement rates apply. The children are considered eligible for free meals without application. Private non-profit organizations which sponsor projects may not operate more than 5 food service sites and may not serve more than 300 homeless children at each site. Public entities sponsoring the project are not subject to these site limitations.

Currently, there are 63 private nonprofit organizations and one public entity sponsoring 96 homeless shelters nationwide. These shelters serve approximately 2,500 preschool age children each day.

The demonstration provided \$6,800 in Fiscal Year 1990, \$92,000 in Fiscal year 1991, and \$344,200 in Fiscal Year 1992. In Fiscal Year 1993, we provided \$936,200, of which, \$286,200 was from recovered SAE funds. We anticipate providing \$2.3 million in Fiscal year 1994, of which, \$1.5 million will be from recovered SAE funds. Applications continue to be accepted and are being reviewed as received.

In a Food and Nutrition Service study of the demonstration in 1990-92, the majority of participating shelters reported that the quality of the meals has improved as a result of the demonstration. Specifically, more milk, fresh fruit, vegetables, and full-strength juices are being served. Even though the demonstration only provides reimbursement for meals served to children under the age of 6, the quality of meals served to older children also often improved since shelter staff are reluctant to serve different meals to older siblings.

Mr. DURBIN. Can we assume that, since there is no budget request to continue this project in fiscal year 1995, it will not be funded?

Mr. LUDWIG. The current authorization for the homeless demonstration expires at the end of the current fiscal year. While the Department has not asked Congress for funds beyond Fiscal Year 1994, the point needs to be made, however, that, if they are reauthorized, there may not be sufficient recovered State Administrative Expense funds available to support it at the current level. In that regard, whether or not additional monies are made available to fund the project, the Department would be pleased to continue to work with Congress to devise ways to meet the nutritional needs of homeless children.

NATIONAL COMMODITY PROCESSING PROGRAM

Mr. DURBIN. The National Commodity Processing program is a program whereby the Department enters directly into agreements with private food processors to convert surplus commodities into a variety of finished products. These processors then sell the products, at reduced prices, to State agencies eligible to receive donated surplus commodities. How much was spent in fiscal year 1993 and how much do you anticipate spending in fiscal year 1994 on this program?

Mr. LUDWIG. For Fiscal Year 1993, the Department of Agriculture distributed an estimated \$393,000 worth of bonus commodities to eligible recipient agencies through the National Commodity Processing Program. For Fiscal Year 1994, we estimate that commodities distributed will be valued at approximately \$303,000, which is a 23 percent decrease from the prior year. Administration of this program requires 4 staff years at a cost of \$182,750 per year.

Mr. DURBIN. Through management evaluations and audits of companies participating in the program, FNS has recovered over \$7.7 million in claims since the program began in fiscal year 1982.

How much is still outstanding? What is being done to collect on these claims?

Mr. LUDWIG. To date, \$28,586 is still outstanding from claims assessed against two processors participating in the program. These claims, for \$8,523 and \$20,063, are in the final stages of collection and should be closed soon.

If processors fail to pay any outstanding balances after receiving three demand letters, the Food and Nutrition Service pursues payment with the appropriate bonding company. Debarment procedures may be an option depending on the circumstances.

PROCESSED COMMODITY INVENTORY MANAGEMENT SYSTEM

Mr. DURBIN. Fiscal year 1993 was the first full year the Processed Commodity Inventory Management System, a tri-agency computer system used to carry out the food distribution programs, was operational. Tell us how this system operates and the benefits that have been realized to date.

Mr. LUDWIG. The Processed Commodity Inventory Management Systems, PCIMS, became fully operational at the Food and Nutrition Service, FNS, in Fiscal Year 1993. The most effective and efficient management of our commodity distribution programs would not be possible without PCIMS. For example, data that, under the old system, could only be accessed by generating a report and waiting 24 hours, can now be accessed on screen immediately. Functions previously done manually or through the old inefficient computer system are now being done more effectively and efficiently in PCIMS. PCIMS increases communication efficiency, and monitors the flow of commodities for the several food distribution programs administered by FNS. FNS, Agricultural Marketing Service, AMS and Agricultural Stabilization and Conservation Service, ASCS, review the availability of various commodities. FNS then uses PCIMS to survey State distributing agencies on commodities needed for their programs. FNS then, in conjunction with orders from the State distributing agencies, provides delivery orders to AMS and ASCS using the PCIMS system. AMS and ASCS procure the commodities through PCIMS based on FNS program needs. AMS and ASCS provide grading and inspection services to ensure contract compliance. ASCS, in addition to procuring certain commodities, coordinates all warehousing and shipping of commodity products as well as all payments to vendors. Most of the accounting functions also take place through the PCIMS system. The next step, to maximize efficiency, will be to establish paperless communications with the States, the shipping contractors and the warehouse companies.

PCIMS is a more completely automated system than the collection of systems which it replaced. Although the basic system is in place and is operational, it is going through a period of changes and enhancements to bring it to a point of maximum efficiency. This is common for a system of this size and complexity. There are savings in data entry time, since the previous systems required significant re-keying. The primary benefits of PCIMS are better control through more accurate, consistent and timely information, better analysis of purchase alternatives, ability to determine the status of an order and quick response to recipient needs. AMS, ASCS,

and FNS are currently in the process of testing a major system enhancement to the tri-agency accounting portion of the system. These enhancements, which are scheduled to be in production this year, will provide the three agencies with more accurate accountability on commitments and expenditures of funds. FNS is currently developing another enhancement which will provide the three agencies with Federal inventory balances by food distribution program and section of public law.

Mr. DURBIN. A pilot project to develop a plan for implementing an electronic data exchange is being planned for fiscal year 1994. Describe this project in further detail for the record.

Mr. LUDWIG. The PCIMS will be piloting electronic data exchange between States, regional offices and Headquarters. Electronic Data Interchange, EDI, is the transmitting of documents from one computer application to another using an industry standard format such as X.12 or EDIFACT. While PCIMS has improved many of its functions, there is still substantial work to be done, particularly in the area of State and regional communications dealing with delivery orders and reporting. Agency needs can be better served and paperwork decreased by utilizing EDI between the States, regional offices and PCIMS Headquarters.

To ascertain the State's and regional office's interest in becoming trading partners in EDI, Food and Nutrition Service PCIMS sent a questionnaire to all FNS regional offices asking them to nominate States to pilot selected EDI applications. After reviewing all nominees, three regions were selected for the pilot project: Mid-Atlantic Regional Office—Maryland, Midwest Regional Office—Indiana, Western Regional Office—Washington.

From the selection process a Regional Office Advisory Group was formed consisting of region and State PCIMS program staff personnel and PCIMS technical personnel. This team, along with the PCIMS Headquarters group comprised of program and technical personnel, will implement EDI as a pilot by December 1994.

BID-RIGGING DEBARMENTS

Mr. DURBIN. Update the Committee on the Department's efforts to suspend or debar companies that are found guilty of bid-rigging in child nutrition programs.

Mr. LUDWIG. In keeping with the Department's previously stated commitment to take administrative action to consider suspending or debarring any company or individual found guilty of bidrigging or other serious offenses as expeditiously as possible, FNS has taken several actions to enhance the Agency's capabilities to deter bidrigging in relation to FNS programs and to enforce the Department's nonprocurement suspension and debarment regulations aggressively, when warranted, to protect the public interest. Paramount among these initiatives is the recent creation of a dedicated task force devoted exclusively to assessing information and making recommendations to the deciding official for the initiation of suspension and debarment actions. The mission of the task force is to vigorously enforce the Department's regulations which permit possible exclusion of individuals and/or corporations that have clearly demonstrated a lack of integrity or who have fraudulently partici-

pated in FNS programs from continued participation in such programs.

FNS has also been active in sponsoring procurement workshops for State and local agencies. These workshops have included sessions on recognizing and dealing with noncompetitive industry practices including bidrigging. Upon completion of the Northeast Regional Office's August 1994 workshop, procurement workshops will have been conducted in all seven of the FNS Regions since December 1992.

Mr. DURBIN. I read in the explanatory notes where two dairies were notified that debarment proceedings would not be initiated due to the protection to FNS programs granted under the Administrative Agreement the companies entered with the Defense Logistics Agency. What does this mean?

Mr. LUDWIG. On August 16, 1993 and on July 21, 1993, the Food and Nutrition Service notified Kinnett Dairies, Inc. and Borden, Inc., respectively, that FNS had made a determination not to initiate debarment proceedings against the companies in view of previously executed administrative agreements between the Defense Logistics Agency, DLA, and the two companies. These agreements were executed by DLA in lieu of procurement debarments against the two companies and contained provisions extending adequate protections not only to Federal procurements but also procurements under Federal grant programs such as the National School Lunch Program. However, we also informed the two companies that FNS could initiate debarment proceedings at any time, should they fail to abide by the terms of their agreement with DLA or should additional causes for suspension or debarment become apparent.

BID-RIGGING PREVENTION

Mr. DURBIN. In addition to receiving commodities from USDA, schools also receive a cash reimbursement for meals served which are used to purchase additional commodities. During the hearing last year with the Office of the Inspector General, I raised a concern I had that the procurement process for both USDA and school food authorities include steps to prevent bid-rigging from occurring. At this time last year the Inspector General stated that an audit was in progress to evaluate procurement practices. When the Inspector General appeared before the subcommittee last month I asked about the status of this audit. What I was told was that the procurement process did not include steps to prevent bid-rigging from occurring. What corrective actions are you taking to change this?

Mr. LUDWIG. The Food and Nutrition Service is taking action to curtail bid-rigging in procurement under its programs, particularly with respect to the child nutrition programs. FNS has been active in sponsoring child nutrition procurement workshops for State and local agencies. These workshops have included sessions on recognizing and dealing with noncompetitive industry practices including bid-rigging. The Department of Justice's, DOJ, Antitrust Division has assisted in this effort by providing written materials and by conducting a session during each workshop emphasizing practical advice on procurement and recordkeeping practices, and recognizing and reporting suspected bid-rigging. Upon completion

of the Northeast Regional Office's August 1994 workshop, procurement workshops will have been conducted in all seven of the FNS Regions since December 1992.

Following training by USDA, State agency staff will continue to provide similar training to local agency personnel. DOJ's Antitrust Division has provided further assistance by developing an article on recognizing antitrust violations which appeared in a school purchasing newsletter published by the Southeast Regional Office and made available to all FNS Regions. FNS also believes that its suspension and debarment activities, which are currently focused on firms and individuals convicted of milk bid-rigging, can have a real different effect on potential bid-rigging in the future. To that end, FNS will publicize all final suspension and debarment actions in addition to providing specific notification to State and, in turn, local cooperating agencies.

EXPIRING BALANCE

Mr. DURBIN. You show an amount of \$27,149,000 expiring at the end of fiscal year 1993. Why didn't this money get spent?

Mr. LUDWIG. The final cost of the Child Nutrition Programs is determined by a combination of the effects of participation and change in the economic indicators. Although we use sophisticated models to project program growth and economic change it's impossible to make the estimate exactly correct. Also the appropriation for this program is available for two years. This provides some uncertainty as to the level of funds which will be carried forward from one year to the next.

CARRYOVER BALANCE

Mr. DURBIN. You also project to carryover \$301,665,716 from fiscal year 1994 into fiscal year 1995. Tell us the reason for this carryover of funds. Provide a breakout, by program, of this carryover amount.

Mr. LUDWIG. The meal service estimates on which the fiscal year 1994 Child Nutrition Program appropriation was based were made in December 1992. Those estimates were made on the basis of the best program and economic data available at that time. Program data has since been revised and additional data has become available. The Office of Management and Budget has also revised its economic assumptions for the budget period. Based on this new information, the Food and Nutrition Service revised its program estimates downward at Mid-Session. The difference between the original program estimates, on which the appropriation was based, and the revised Mid-Session estimates accounts for the large carryover projected for fiscal year 1994. The majority of the difference occurred in the School Lunch and Child and Adult Care Food programs.

DISCRETIONARY ADDITIONS

Mr. DURBIN. The budget request includes \$32,529,000 in discretionary additions to the mandatory baseline. Provide a table for the record showing the baseline and the additions in each subsequent year including the fiscal year 1995 request.

Mr. LUDWIG. The information is being submitted on a current services basis for the record.

[The information follows:]

	1991 base	(+/-)	1992 BA	(+/-)	1993 BA	(+/-)	1994 BA	(+/-)	1995 BA
Studies	3,085	+750	3,835	0	3,835	0	3,835	-172	3,663
Nutrition education	7,500	+2,500	10,000	0	10,000	+270	10,270	0	10,270
Coord. review effort	3,653	+430	4,083	-303	3,780	+69	3,849	0	3,849
Food service mgt. institute	1,143	+179	1,322	+339	1,661	+192	1,853	-147	1,706
Dietary guidelines ..	0	0	0	+2000	2,000	+54	2,054	+18,443	20,497
Computer support ..	1,800	-900	900	-250	650	+612	1,262	0	1,262
AMS admn.	100	0	100	0	100	+370	470	+249	719
ASCS admn.	499	+276	775	+29	804	+671	1,475	+461	1,936
PCIMS	786	+214	1,000	-158	842	+1,674	2,516	+815	3,331
Cash/cloc	0	0	0	0	0	+162	162	0	162
Kentucky/lowa demo	0	0	0	+3,700	3,700	0	3,700	0	3,700
Total	18,566	+3,449	22,015	+5,357	27,372	+4,074	31,446	+19,649	51,095

APPLICATION UNIFORMITY

Mr. DURBIN. Each of the child nutrition programs use the same income poverty thresholds and have similar administrative procedures, in fact some entities operate several programs at the same time. If this is the case, then why can't each program use the same application form and process?

Mr. LUDWIG. The household applications are, in fact, the same for the National School Lunch, School Breakfast and Special Milk Programs and for the portion of the Child and Adult Care Food Program that pertains to children. When a school or other sponsor operates multiple programs the same application may be used. In the Summer Food Service Program, the eligibility of the site is the important factor rather than household eligibility. When applications are used in the Summer Food Service Program, such as in camps or enrolled sites, the forms are the same as those used in schools and child care facilities.

The applications for sponsoring organizations differ by program since each program has different legislative and regulatory administrative requirements. However, this is an area that we are reviewing.

SOFTWARE RENEWAL SYSTEMS

Mr. DURBIN. The notes state that funds were provided for computer support activities to assist in the transition from contractor to FNS in-house maintenance of Special Nutrition programs software renewal systems. Would you please elaborate on this statement in further detail for the record.

Mr. LUDWIG. The Software Renewal Program, SRP has been successful—remaining within budget and on or near schedule—in dramatically enhancing the information architecture to support the Agency's critical program mission and immense fiduciary responsibility.

The SRP has been accomplished with a partnership between Government and industry. The Agency's systems personnel maintained the previous generation's 66 stand-alone systems until they were replaced by the four new integrated SRP systems that were developed by contractor personnel.

FNS currently has a transition strategy underway whereby contractor personnel serve as "mentors" to the Food and Nutrition Service systems staff to prepare them to assume maintenance of segments of the new SRP systems. However, since the SRP systems provide a six-fold increase in functionality over the predecessor systems, FNS systems staff can not, at current levels, assume full responsibility for the new SRP systems.

DEMONSTRATIONS, STUDIES, AND REPORT

Mr. DURBIN. In last year's hearing record, you provided the Committee with a list of all demonstrations, studies, and reports that were mandated by P.L. 101-147, as well as the results of those that were completed. Please update this list for the record.

Mr. LUDWIG. I will include for the record an update of the list of demonstrations, studies, and reports mandated by Public Law 101-147.

[The information follows:]

Last year, the Food and Nutrition Service (FNS) reported the status of 17 demonstrations, studies, and reports mandated by P.L. 101-147. At that time, 11 of the 17 projects had already been completed. This year, I will report on the remaining six.

I. Child Nutrition Programs

Demonstrations

Alternate Counting Methods Pilot Projects

This demonstration in 10 sites seeks alternatives to financial accountability systems involved in administering programs under the National School Lunch and Child Nutrition Acts by testing alternative methods for the application process as well as methods to count and claim meals.

Completion Date: Fall 1994

Estimated Costs: Operations \$0
Evaluation \$850,000

Studies and Reports

School Breakfast Program Outreach Grant

The objectives of the School Breakfast Program Outreach Grant Study are to: examine the changes in school and student participation as a result of the grants; determine what expenditures the schools made with grant funds; and describe the characteristics of schools receiving grants. The study will use the quarterly expenditure reports and year-end reports submitted by the schools to conduct the analysis. An analysis plan identifying the key data elements has been developed. The analysis plan has also identified additional data elements that should be collected in the year-round reports. This is the last year of the grants unless extended in the 1994 Reauthorization.

Completion Date: June 1994.

Estimated Costs: Evaluation \$600,000

II. WIC Program

Studies and Reports

Estimates of Women, Infants, and Children Eligible for the Special Supplemental Food Program for Women, Infants and Children

This report will produce estimates of persons who are income eligible for WIC at the national, State, and county levels based on 1990 Census and other data.

Completion Date: Fiscal Year 1994

Estimated Costs: \$516,240

III. Summary of Completed Research

The Homeless Shelter Demonstration

This homeless shelter demonstration was designed to determine the feasibility of providing year-round food assistance to preschool children (under age 6) in homeless shelters. Unlike older homeless children, preschoolers do not have access to school meals.

The first phase of this demonstration was initiated in 1990 in four shelters operated by the same sponsor. An evaluation of the first 9 months of the demonstration, covered in the Year 1 report, concluded that the demonstration offered a feasible way to provide year-round nutrition to homeless preschool children.

The Year 2 report covers FNS's 1991 expansion of the demonstration to include 8 additional sponsors and 13 additional shelters. The Year 2 study determines the feasibility of the demonstration based on the experiences of a larger number of sponsors and shelters. Key findings are (1) all participating shelters were able to operate the program (prior experience with Federal nutrition programs helped, however); and (2) the majority of participating shelters reported that meal quality increased as a result of the demonstration. They added more milk, fresh fruit, vegetables, and full-strength juices.

For-Profit Center Demonstrations

State-wide demonstrations were conducted in Kentucky and Iowa to determine what effect a change in for-profit center eligibility might have on the participation of low-income children. The change involved switching eligibility criteria from requiring that at least 25 percent of enrolled children receive Title XX subsidies to requiring that 25 percent be from families with incomes at or below 185 percent of the Federal poverty level. Centers that participated in the demonstration were required to either reduce their fees or improve the quality of meals they served.

Some of the major findings are: (1) the demonstration increased the participation of for-profit centers in both states; (2) the demonstration increased the number of low-income children receiving CACFP in both states; and (3) the demonstration improved the quality of meals and supplements.

Low-Income Family Day Care Home Demonstration

Family day care homes (FDCHs) that operate in low-income areas or serve primarily low-income children are underrepresented in CACFP. This demonstration first identified likely barriers to participation in CACFP by low-income FDCHs. It then went on to test three approaches to removing barriers and increasing participation.

Lack of awareness of CACFP is a major barrier to participation by low-income providers. Isolation and literacy problems, which contribute to lack of awareness, preceded the complexity of the licensing procedure as barriers. It was also found that outreach to low-income population differs from outreach to the general population. Intensive one-on-one assistance is an effective strategy to recruit low-income providers in the demonstration sites.

OUTLETS AND AVERAGE DAILY PARTICIPATION

Mr. DURBIN. Please update the table that appears on page 227 of last year's hearing record showing the number of outlets and average daily participation for the school lunch, school breakfast, and child and adult care food programs to include fiscal year 1993.

Mr. LUDWIG. I will provide the information for the record.

[The information follows:]

NATIONAL SCHOOL LUNCH, SCHOOL BREAKFAST, AND CHILD AND ADULT CARE FOOD PROGRAMS
Outlets and Average Daily Participation, Fiscal Years 1980 through 1993 1/

Fiscal Year	National School Lunch Program		School Breakfast Program		Child and Adult Care Food Program Child Care		Adult Care	
	Outlets (October)	Average Daily Participation	Outlets (October)	Average Daily Participation	Averages of Quarterly: Outlets Attendance	Averages of Quarterly: Outlets Attendance	Outlets	Attendance
1980	94,376	26,607,666	32,846	3,585,445	36,517	659,358		
1981	93,960	25,823,667	35,079	3,810,333	57,625	777,667		
1982	91,162	22,940,445	34,352	3,043,111	68,500	844,875		
1983	90,586	23,185,191	33,534	3,376,969	73,825	909,350		
1984	89,614	23,376,276	33,840	3,428,162	84,250	982,275		
1985	89,424	23,573,475	34,795	3,437,169	93,512	1,046,723		
1986	89,857	23,719,123	35,180	3,497,060	99,256	1,100,543		
1987	90,180	23,938,835	37,161	3,609,679	107,590	1,185,549		
1988	90,608	24,210,022	38,816	3,680,589	120,235	1,255,721	213	6,605
1989	91,493	24,187,218	40,029	3,813,489	135,491	1,358,314	365	10,493
1990	91,325	24,133,381	42,766	4,068,692	152,068	1,472,712	634	17,270
1991	91,620	24,213,249	46,140	4,437,150	168,710	1,618,425	1,031	26,495
1992	92,660	24,605,890	50,598	4,918,525	186,650	1,789,140	1,145	31,598
1993	93,059	24,850,191	55,437	5,357,362	200,826	1,941,357	1,204	34,827

1/ Outlet data for National School Lunch and School Breakfast Programs are reported only in October. Their ADP, a number estimated by increasing reported ADM (average daily meals) using an absentee factor, is a school year average (Sept-May) of those estimates. The ADP number assumes no absentees -- that all students participating were actually at school that day. Outlets and attendance are reported quarterly for the Child and Adult Care Food Program. The numbers above are averages of those quarterly numbers.

Prepared: 3/17/1994

Source: FNS 10 and FNS 52 reports.

Mr. DURBIN. Also, update the tables that appear on pages 229 and 230 to reflect fiscal year 1993 actuals and fiscal year 1995 estimates.

Mr. LUDWIG. This information will also be submitted for the record.

[The information follows:]

CHILD NUTRITION PROGRAMS
Average Daily Participation for
Fiscal Years 1990 through 1995

Child Nutrition Programs	Fiscal Year	Average Daily Participation			
		below 130% of poverty	130% to 185% of poverty	above 185% of poverty	Total
National School Lunch Program	FY 1990	9,896,149	1,653,937	12,583,295	24,133,381
	FY 1991	10,293,053	1,762,641	12,157,555	24,213,249
	FY 1992	11,221,337	1,723,618	11,660,935	24,605,890
	FY 1993	11,774,127	1,742,463	11,333,601	24,850,191
	FY 1994 1/	11,869,419	1,756,565	11,425,327	25,051,311
	FY 1995 1/	11,966,750	1,770,969	11,519,017	25,256,736
School Breakfast Program	FY 1990	3,297,768	219,086	551,838	4,068,692
	FY 1991	3,610,062	251,521	575,567	4,437,150
	FY 1992	4,054,591	259,572	604,362	4,918,525
	FY 1993	4,410,929	282,087	664,346	5,357,362
	FY 1994 1/	4,881,226	312,163	735,179	5,928,568
	FY 1995 1/	5,131,763	328,186	772,913	6,232,862
Child and Adult Care Food Program 2/	FY 1990	1,168,619	66,789	237,304	1,472,712
	FY 1991	1,299,450	67,043	251,933	1,618,425
	FY 1992	1,458,197	68,375	262,568	1,789,140
	FY 1993	1,585,237	72,860	283,260	1,941,357
	FY 1994 1/	1,811,926	85,100	324,899	2,221,926
	FY 1995 1/	2,060,993	93,533	357,200	2,511,727
Summer Food Service Program	FY 1990	1,689,957			1,689,957
	FY 1991	1,839,674			1,839,674
	FY 1992	1,916,359			1,916,359
	FY 1993	2,106,419			2,106,419
	FY 1994 1/	2,253,127			2,253,127
	FY 1995 1/	2,386,467			2,386,467

1/ Projected data.

2/ Only total attendance is reported for CACFP, so the categories must be estimated for all years.

Prepared: 3/22/94

Source: State-reported data from forms FNS 10, 44, and 418.

CHILD NUTRITION PROGRAMS
Number and Type of Meals Served
Fiscal Years 1990 through 1995
(Meals in 000's)

Meals served to children where family income is:					
Child Nutrition Programs	Fiscal Year	below 130% of poverty	130% to 185% of poverty	above 185% of poverty	Total
National School Lunch Program	FY 1990	1,661,596	273,016	2,074,464	4,009,076
	FY 1991	1,748,830	292,517	2,009,927	4,051,273
	FY 1992	1,881,653	284,557	1,925,883	4,092,093
	FY 1993	1,980,585	287,723	1,869,407	4,137,714
	FY 1994 1	2,049,007	291,221	1,844,209	4,184,437
	FY 1995 1	2,066,075	293,400	1,859,002	4,218,477
School Breakfast Program	FY 1990	576,334	37,155	94,036	707,525
	FY 1991	631,577	42,838	97,795	772,210
	FY 1992	702,902	43,650	102,365	848,917
	FY 1993	763,472	47,375	112,325	923,171
	FY 1994 1	819,393	50,377	121,201	990,971
	FY 1995 1/	861,274	53,231	127,083	1,041,588
Child and Adult Care Food Program a/	FY 1990	766,860	43,894	155,581	966,336
	FY 1991	853,549	44,152	165,141	1,062,843
	FY 1992	963,566	45,363	173,027	1,181,956
	FY 1993	1,058,353	48,867	188,556	1,295,777
	FY 1994 1/	1,229,422	57,099	216,357	1,482,878
	FY 1995 1/	1,375,674	62,757	237,867	1,676,298
Summer Food Service Program	FY 1990	91,218			91,218
	FY 1991	96,218			96,218
	FY 1992	107,448			107,448
	FY 1993	113,239			113,239
	FY 1994 1	117,351			117,351
	FY 1995 1	124,296			124,296

1/ Projected data.

a/ Includes Adults Served Under the Program

~~Prepared: 3/23/84~~ 

Source: State-reported data from forms FNS 10, 44, and 418.

CNP STUDIES

Mr. DURBIN. Please update the list of all ongoing child nutrition studies that was provided last year to include a summary of results from those completed in fiscal year 1993 and any new studies initiated in fiscal year 1994.

Mr. LUDWIG. I will include for the record an updated list of Child Nutrition Studies that were ongoing during Fiscal Year 1993, a list of Child Nutrition Studies planned for Fiscal Year 1994, and the summaries of Child Nutrition Studies completed since last year's submission.

[The information follows:]

Ongoing Child Nutrition Studies

FOOD SERVICE MANAGEMENT COMPANIES

This study examines the range of experiences of School Food Authorities (SFAs) that have contracted with food service management companies and the contractual agreements and oversight responsibilities for food service management company operators. The intent is to learn advantages and disadvantages of this method of providing food service as compared to traditional self-managed operations in order to develop improved guidance and direction to States and SFAs. An interim report is presently in Agency clearance, however, a final report will be placed in clearance soon.

Estimated Completion Date: Fall 1994
 Amount Obligated Through Fiscal Year 1993: \$853,355
 Congressionally Mandated: No

STUDY OF SCHOOL LUNCH ELIGIBLE NON-PARTICIPANTS

This study will examine why eligible students don't apply for, or eat, free and reduced-price meals. Results of this study should allow the Secretary to assess what more should be done to reach all eligible students. By means of case study methodology, this study will examine the reasons why those income-eligible to participate in the school lunch program fail to do so. Potential barriers (real and perceived) will be examined by directly interviewing non-participant households. The study will also recommend ways to reduce barriers and increase daily participation. This study was recommended by Congress in the 1990 Farm Bill pending availability of funds.

Expected Completion Date: Summer 1994
 Amount Obligated Through Fiscal Year 1993: \$377,833
 Congressionally Mandated: Yes; P.L. 101-624

ALTERNATE MEAL COUNTING AND CLAIMING

Public Law 101-147 amended the National School Lunch Act to require the Secretary to conduct three pilot programs seeking to simplify and reduce meal counting and claiming requirements in the National School Lunch Program. Ten sites are currently involved in this demonstration. The evaluation design calls for a pretest-posttest case study approach. Baseline data was collected during School Year 1991. Alternative application and meal counting procedures began in School Year 1992. This evaluation requires data collection and analysis in all 10 sites through 1994. Data will continue to be collected through 1994, however, an interim report on the first two years is currently in Agency clearance and will be available soon.

Expected Completion Date: Fall 1994
 Amount Obligated Through Fiscal Year 1993: \$853,996
 Congressionally Mandated: Yes; P.L. 101-147

SCHOOL LUNCH AND BREAKFAST COST STUDY

The purpose of this study is to determine the cost to produce reimbursable meals in the National School Lunch Program (NSLP) and the School Breakfast Program. In addition, the study will examine the indirect costs charged to School Food Authorities to produce school meals, and local administrative costs and sources of non-Federal revenue that support meal production.

Estimated Completion Date: Spring 1994
 Amount Obligated Through Fiscal Year 1993: \$1,542,316
 Congressionally Mandated: Yes; P.L. 101-624

MULTI-USE APPLICATION DEMONSTRATION

The State of West Virginia is testing new methods of providing enhanced services to children in need. To this end, they have developed a multi-use application for free and reduced price National School Lunch Program meals that includes a series of waivers to allow income information to be shared with other agencies that provide services to low-income children. FNS entered into a cooperative agreement with the West Virginia State Department of Education to assess whether or not controlled sharing of information has any effect (e.g., presents a barrier or an inducement) on application and participation rates in the National School Lunch Program (NSLP).

Estimated Completion Date: Fall 1994
 Amount Obligated Through Fiscal Year 1993: \$50,000
 Congressionally Mandated: No

NSLP SCHOOL DROPOUT STUDY

This study will examine why schools chose not to participate in the National School Lunch Program. The study will include both schools which have recently dropped out of the program and those which are longtime nonparticipants. The final report will include a description of the scope of the dropout/nonparticipation problem; the reasons for and the decision-making process for dropout and nonparticipation; and the characteristics of dropout/nonparticipation schools.

Estimated Completion Date: Summer 1994
 Amount Obligated Through Fiscal Year 1993: \$360,889
 Congressional Mandate: Yes

UNIVERSAL FREE LUNCH STUDY

The Senate passed resolution in July of 1992 asking the Secretary of Agriculture to conduct a study of various options for

implementing and funding universal school lunch and breakfast programs, i.e., all lunches and breakfasts reimbursed at one rate (with no regard to income status) and served at no charge to students.

Estimated Completion Date: Summer 1994
 Amount Obligated Through Fiscal Year 1993: None
 Congressionally Mandated: Yes; Senate Resolution 303 (7/92)

SPECIAL NUTRITION ANALYSIS AND MODELING-II

This contract will provide quick response capability for the Child Nutrition Programs in answering questions posed by legislators or policy makers. This contract will be used for many purposes, including responding to reauthorization questions and providing cost estimates. Research questions will include characteristics of program eligibles; characteristics of program participants and institutions that administer programs; and the effect of child care expansion legislation. The analyses would use existing data available from national studies, demonstrations or special projects.

Estimated Completion Date: Winter 1994
 Amount Obligated Through Fiscal Year 1993: \$242,032
 Congressionally Mandated: No

EARLY CHILDHOOD AND CHILD CARE STUDY

This study will examine the nutritional content of the meals offered in family day care homes and centers. It will examine the relationship between the current meal pattern and the nutritional needs of child care participants. Additionally, the nutritional contribution of those meals will be determined. Dietary intake data will be collected to determine the contribution of the meals to children's daily dietary intake. The extent of implementation of the Dietary Guidelines will be examined. Additionally, this study will provide data on the characteristics of participants and institutions participating in the program, with an emphasis on nutrition education initiative activities.

Estimated Completion Date: Spring 1996
 Amount Obligated Through Fiscal Year 1993: \$2,893,415
 Congressionally Mandated: No

New Child Nutrition Studies

NUTRIENT STANDARD MENU PLANNING DEMONSTRATION EVALUATION

The Department will conduct a demonstration project testing an alternative to the traditional meal pattern established in program regulations. This alternative, Nutrient Standard Menu Planning (NSMP), requires school meals served during a particular menu cycle to meet the specific standards for school lunches of one-third of the RDA for specific nutrients, one-fourth RDA goal for school breakfasts as well as implementing the Dietary Guidelines for Americans. It is expected that 35 School Food Authorities will participate in this NSMP Demonstration for a three year period beginning in the 1994-95 school year.

During the first year of implementation, this evaluation will document the NSMP operational procedures that were implemented, identify problem areas and changes that were made to improve operations, and provide FNS information on difficulties that might be encountered if the Agency were to expand this alternative.

This evaluation will also assess some major questions about the impact of NSMP on nutrient content and cost of school meals. These questions will be assessed by comparing baseline (pre-test) measures with follow-up (post-test) measures taken after the NSMP has been implemented.

STATE AND LOCAL ADMINISTRATIVE COST STUDY

The primary objective of this study is to examine the changes in the responsibilities of State level staff administering the National School Lunch Program and School Breakfast Program and the costs associated with these changes. A survey will be conducted with all State Child Nutrition Directors to examine a number of issues related to the administration of the school lunch and breakfast program including the organization of the State agencies, their functional responsibilities, budget process and fiscal behavior of the State agencies, and the perceptions of State agency officials about the appropriateness of State Administrative Expense (SAE) funding. FNS program data will be used to document changes in the amount of SAE funding over the past several years.

NUTRITION MEDIA CAMPAIGN

This project will develop national nutrition education media messages that reach young people with nutrition information that is lively and entertaining.

COMPETITIVE NUTRITION EDUCATION COMMUNITY CHALLENGE GRANTS

Through a competitive award process, FNS will seek five demonstration communities (three urban and two rural) in which an alliance of community partners--food retailers, food banks,

private assistance agencies, media and employers--make a commitment, in cooperation with government agencies, to identify hunger and dietary problems, develop comprehensive solutions through joint and coordinated efforts, and integrate nutrition education messages into all alliance contracts with recipients. Other parts of USDA (e.g., HNIS, ES) and DHHS will be solicited as partners. An independent process evaluation will also be funded to assess factors that lead to alliance success.

NUTRITION EDUCATION IN SCHOOLS

This would be a nationally representative survey of nutrition education available in schools. The survey would include an examination of the nutrition education available for school food service workers, teachers, and students. FNS will solicit participation of the Department of Education. The goal of the project is to determine what nutrition education programs, services, and activities are available in the schools.

SCHOOL HEALTH AND MONITORING INITIATIVE

FNS and CDC have joint responsibility for testing the feasibility of a school nutrition monitoring system as prescribed in the 10-year Plan for Nutrition Monitoring. The plan addresses numerous areas including nutrition knowledge, dietary intake, and anthropometry. Initial funding would be used for a pretest of instruments in three or four sites. FNS and CDC will share responsibility for funding, planning, and analysis of the pretest.

Completed Child Nutrition Studies

ADULT DAY CARE STUDY

This study provides a nationally-representative description of the adult component of the Child and Adult Care Food Program (CACFP). The report provides (1) a description of adult day care centers and clients participating in CACFP, including the clients' dietary intake; (2) comparisons of centers and clients participating and not participating in CACFP; (3) an assessment of the contribution of program reimbursable meals to the dietary intakes of clients; (4) an examination of reasons for nonparticipation of centers; and (5) an assessment of prospects for program growth.

Some of the major findings are:

- Overall, 31 percent of adult day care centers operating in 1991 participated in CACFP; 43 percent of centers eligible for the program participated.
- CACFP centers provide approximately three meals and snacks

per day. The most frequent meal patterns are breakfast, lunch, and afternoon snack (27 percent); morning snack, lunch, and afternoon snack (20 percent); and lunch only (18 percent).

- The adult component of the CACFP is attaining its objective of supplying lunches that provide at least one-third of the RDA to participants.
- Intakes of fat and saturated fat from CACFP reimbursable meals exceed the levels recommended in the DHHS/USDA Dietary Guidelines. The intake of carbohydrate is lower and the intake of sodium exceeds the levels recommended in the National Research Council's (NRC) guidelines. The intake of cholesterol is within NRC's recommended range.
- The main reasons for center nonparticipation are: (1) lack of knowledge or information on the program; (2) center ineligibility for the program, because of such factors as lack of licensing or not providing meals; and (3) perceived burden of record keeping in relation to reimbursement levels.

FOR-PROFIT CENTER DEMONSTRATIONS

State-wide demonstrations were conducted in Kentucky and Iowa to determine what effect a change in for-profit center eligibility might have on the participation of low-income children. The change involved switching eligibility criteria from requiring that at least 25 percent of enrolled children receive Title XX subsidies to requiring that 25 percent be from families with incomes at or below 185 percent of the Federal poverty level. Centers that participated in the demonstration were required to either reduce their fees or improve the quality of meals they served.

Data collection included (a) mail surveys of State Agencies to collect data on budgetary impact of the change in eligibility, and outreach strategies targeted to for-profit centers; and (b) pre- and post-demonstration mail surveys of demonstration centers to collect data on characteristics of children served, meals served, and child care fees.

Some of the major findings are:

- The demonstration increased the participation of for-profit centers in both states.
- The demonstration increased the number of low-income children receiving CACFP in both states.
- The demonstration improved the quality of meals and supplements. The percentage of centers meeting the CACFP

meal pattern for 10 days rose.

- No centers reduced prices charged to children

THE HOMELESS SHELTER DEMONSTRATION YEAR ONE REPORT

This homeless shelter demonstration was designed to determine the feasibility of providing year-round food assistance to preschool children (under age 6) in homeless shelters. Unlike older homeless children, preschoolers do not have access to school meals.

The first phase of this demonstration was initiated in 1990 in four shelters operated by the same sponsor.

Key findings are:

- Although all four shelters provided meals to residents prior to the demonstration, the quality of the meals provided to children under age 6 was enhanced, and resources were freed up so that the nutritional value of the meals of older children and adults could be improved.
- All shelters reported that more fruits and vegetables were served as a result of the demonstration.
- All children received fresh fluid milk at every breakfast and lunch. Prior to the demonstration only one of the four shelters provided amounts of milk that were compatible with CACFP meal pattern requirements.
- Shelters reported that they incurred minimal additional expenses for the project. No additional staff were needed.

CHILD NUTRITION HOMELESS DEMONSTRATION--YEAR TWO REPORT

This homeless shelter demonstration was designed to determine the feasibility of providing year-round food assistance to preschool children (under age 6) in homeless shelters. Unlike older homeless children, preschoolers do not have access to school meals. The Year 2 study found that all participating shelters were able to operate the child nutrition program, and that meal quality increased as a result of the demonstration.

LOW-INCOME FAMILY DAY CARE HOME DEMONSTRATION

Family day care homes (FDCHs) that operate in low-income areas or serve primarily low-income children are underrepresented in CACFP. This demonstration first identified likely barriers to participation in CACFP by low-income FDCHs. It then went on to test the following three approaches to removing barriers and increasing participation.

- Strategy A was designed to eliminate licensing barriers. Among licensing barriers are licensing fees and the cost of bringing homes up to licensing standards.
- Strategy B was designed to alleviate program barriers by coordinating CACFP with various governmental and nongovernmental agencies that administer child care programs.
- Strategy C was designed to reduce educational, language, and distance barriers to low-income FDCH participation. These demonstrations focused on innovative technical assistance and outreach strategies tailored to FDCH providers in specific populations, including providers with limited education or that operate in rural areas.

The year-long demonstration was conducted in six target areas. A pre- and post-test case study method allowed comparisons of change between target areas and either the states they were in, or the sponsorship areas they were in. Measures of change focused on the number of new homes recruited and the number of homes submitting claims for meal reimbursements. Data were also collected from State Agency demonstrators, their sponsors, and sponsors that conducted demonstrations.

Some of the major findings include:

- Lack of awareness of CACFP is a major barrier to participation by low-income providers. Isolation and literacy problems, which contribute to lack of awareness, preceded the complexity of the licensing procedure as barriers.
- Demonstrations were able to recruit providers that serve low-income children and/or that operate in low-income areas into CACFP. In most instances, the rate of growth in target areas surpassed surrounding states and sponsorships. Two-thirds of recruited FDCHs were still in CACFP six-months after the demonstration ended.
- Outreach to low-income population differs from outreach to the general population. Intensive one-on-one assistance is an effective strategy to recruit low-income providers in the demonstration sites. Personal outreach should be conducted by persons familiar with the target area.
- Financial assistance is effective.
- Coordination with other agencies supports recruitment of low-income providers.

MENU MODIFICATION DEMONSTRATION GRANTS: EVALUATION RESULTS

The Food and Nutrition Service (FNS) sought to learn more about what school districts could accomplish on their own to plan and serve meals that better reflect the Dietary Guidelines. FNS competitively awarded five grants to school districts that had not previously made major nutritional improvements so that the modification process could be tracked and effects evaluated in "typical" school food service. Four districts modified lunch and one breakfast. The project period was School Years 1989-90 to 1991-92.

Both nutritional effects and the process of making changes were examined in the evaluation. Baseline data were collected prior to any menu changes and follow-up data on modified meals were collected in the third project year. Primary data sources were on-site meal observations of foods offered, selected and consumed, interviews with project staff, and 24-hour dietary recalls with 5th graders at the four lunch sites. Approximately 180-200 students were interviewed for pre- and posttest dietary recalls at each site.

Some of the meal content findings are:

- Modified meals contained less fat than those offered prior to the demonstration in all districts. However, calories were considerably reduced as well.
- The proportion of calories from fat changed little due to reductions in both fat and calories.
- Therefore, a critical step in developing menus that comply with the Dietary Guidelines appears to be replacing calories lost due to fat reduction with complex carbohydrate calories (fruits, vegetables, grains). This will maintain calories while also diminishing the proportion provided by fat.
- Both baseline and modified lunches met the program goal of one-third of the RDA for vitamins and minerals, with few exceptions. Over 24-hours, most students obtained the RDA for any nutrients that fell short at lunch.

CHILD NUTRITION PROGRAM OPERATIONS STUDY: YEAR THREE REPORT

This three-year panel study was designed to provide descriptive data on Child Nutrition Program characteristics from a nationally representative sample of 1,740 School Food Authorities (SFAs). The third year of the study provides a snapshot of school-based Child Nutrition Programs during School Year 1990-91. This study describes participation in the National School Lunch Program and the School Breakfast Program; meal prices; operations of the Food Donation Program; training and technical assistance; commercial food service vendors; and after-school care. Some of the major findings include:

- The overall student participation in the NSLP remained

relatively constant between School Year 1987-88 and School Year 1989-90. Overall participation was estimated to be 58 percent for School Year 1989-90. Estimates of participation rates for free, reduced-price, and paid children were 85 percent, 69 percent, and 46 percent respectively.

- The School Breakfast Program (SBP) continues to be available to an increasing number of students. In School Year 1989-90, over 700 million breakfasts were served. Both the number of SFAs and schools offering the program is increasing.
- The average price for a full-price NSLP meal during School Year 1989-90 increased 7-10 cents from the previous year to \$1.02 in elementary schools and \$1.16 in secondary schools. The average price charged for a full-price SBP meal in SY 1990-91 also increased about 2-3 cents to \$.52 in elementary schools and \$.55 in secondary schools. The average price for a reduced-price lunch and breakfast remained relatively stable at \$.38 and \$.27, respectively with little variation across grade levels.
- Based on SFA aggregates, about 20 percent of all SFAs had claiming ratios of 100 percent or more in SY 1990-91. This means, that on average, these SFAs claimed more meals than they had applications on file. While potential overclaimed meals represent a relatively small percentage (1.6 percent) of the total number of free meals served nationally, this represents a maximum loss to the program due to overclaiming free meals of about \$45 million.
- Almost all SFAs (88 percent) reported that reductions in the level of bonus commodity donations had affected their food service operations. Almost all SFAs reported that they increased commercial food purchases with many now purchasing processed cheese (92 percent), non-fat dry milk (59 percent) and mozzarella cheese (55 percent).

SCHOOL NUTRITION DIETARY ASSESSMENT STUDY

This study presents findings on the nutrients and foods provided in school meals, and describes the dietary intakes of the nation's students on a typical school day. The study collected information from a nationally representative sample of 545 schools and 3,350 students attending those schools. Schools provided information about all meals served during a one-week period between February and May 1992, as well as information about school food service operations. Approximately 3,350 students in grades 1 through 12 provided detailed information about the foods and beverages they consumed during a 24-hour period that included a school day.

The study compared the nutrients provided in school meals and the

nutrients consumed by students with several standards: the RDAs that are used to plan school meals, recommendations for fat and saturated fat from the *Dietary Guidelines for Americans*, and sodium, cholesterol and carbohydrate recommendations of the National Research Council (NRC) published in *Diet and Health*.

Some of the major findings are:

Meals as Offered:

- NSLP lunches provide one-third or more of the RDA for key nutrients--calories, protein, Vitamins A, C and B6, calcium, iron and zinc.
- Calories from fat--38 percent--and saturated fat--15 percent--exceed the Dietary Guideline goals of 30 percent or less from fat and less than 10 percent from saturated fat.
- The average amount of sodium in school lunches is almost 1,500 milligrams (mg) which is nearly two-thirds of the NRC recommendation of less than 2,400 mg per day.
- The average amount of cholesterol in lunches is 88 mg which meets NRC recommendations.
- Virtually no schools conformed to the Dietary Guideline goals for fat and saturated fat. Only one percent of schools offered lunches that provide an average of 30 percent or less of calories from fat. Less than one percent of schools provide an average of 10 percent or less of calories from saturated fat.

Dietary Intake of NSLP Participants:

- Students who consumed a NSLP school lunch averaged one-third or more of the daily RDA for calories, vitamins and minerals.
- NSLP participants consumed an average of 37 percent of calories from fat and 14 percent of calories from saturated fat.
- Students who consumed lunches from other sources than the NSLP consumed 33 percent of calories from fat.
- NSLP participants average consumption of sodium was 1479 mg - almost double the lunch target of 800 mg.
- NSLP participants are more than twice as likely as nonparticipants to consume milk and milk products at lunch. Nonparticipants are more likely to obtain their carbohydrate from sweets and sweetened drinks, while NSLP participants

are more likely to obtain their carbohydrate from milk and vegetables.

Average daily intake for all students on a typical school day.

- On average, students' daily intake exceed the RDA for calories--a finding that holds for all income groups.
- The average daily percent of calories from fat consumed by all students is 34 percent and 13 percent from saturated fat. Students from low-income families have higher percentages of calories from fat than students from higher-income families.
- Students' daily intakes of sodium at 4,633 mg are almost twice the NRC recommendation of less than 2,400 mg per day.
- Students' daily intake of cholesterol at 299 mg meets the NRC recommendation of 300 mg or less.

CLOC PROGRAMS

Mr. DURBIN. The Cash and Commodity Letter of Credit, CLOC, programs are scheduled to end at the end of this fiscal year. Are you proposing that they be extended when the child nutrition programs are reauthorized this year?

Mr. LUDWIG. The Commodity Letter of Credit and Cash-In Lieu of Commodities pilot projects have been in operation for over ten years. We are aware that the projects are scheduled to end at the end of the fiscal year. At this time the Department does not anticipate initiating legislation to extend the projects.

SPECIAL MILK

Mr. DURBIN. Is there a requirement, similar to the mandate in the child nutrition programs, to provide whole milk as an option in the special milk program?

Mr. LUDWIG. The Special Milk Program allows sponsors to choose the type of pasteurized fluid milk to be offered, provided that the milk meets State and local standards.

Mr. DURBIN. What kind of milk is offered through this program? Provide a breakout of the type of milk served in the program and the number of half-pints used for each type.

Mr. LUDWIG. In the Special Milk Program, sponsors may offer pasteurized fluid types of unflavored or flavored whole milk, low-fat milk, skim milk, or cultured buttermilk. There has not been a study of the special milk program. Therefore, we do not have data on the types of milk that are actually being served, and we do not believe that anyone, other than individual schools or school districts, maintains this data.

Mr. DURBIN. You show a balance of \$2,198,609 expiring at the end of fiscal year 1993. What is the reason these funds were not used?

Mr. LUDWIG. At the end of Fiscal Year 1993 a balance of \$2,918,609 expired due to changes in program performance. Actual program participation was lower than we anticipated. Therefore, funds required to support the program decreased accordingly.

Mr. DURBIN. How many schools and institutions participate in the special milk program?

Mr. LUDWIG. I will submit the information for the record.

[The information follows:]

SPECIAL MILK PROGRAM OUTLETS OPERATING BY TYPE ¹

Fiscal year	Number			
	Schools	Institutions	Summer camps	Total
1980	86,064	1,056	3,218	90,338
1981	83,646	1,057	3,190	87,893
1982	6,577	284	2,369	9,230
1983	5,895	287	2,392	8,574
1984	5,593	337	2,377	8,307
1985	5,655	330	2,503	8,488
1986	5,462	337	2,373	8,172
1987	5,775	354	2,257	8,386
1988	9,493	417	2,225	12,135
1989	9,281	319	2,022	11,622
1990	9,617	327	2,017	11,961

SPECIAL MILK PROGRAM OUTLETS OPERATING BY TYPE ¹—Continued

Fiscal year	Number			
	Schools	Institutions	Summer camps	Total
1991	10,167	340	1,940	12,447
1992	10,017	355	2,037	12,409
1993	9,017	354	1,908	11,279

¹ Data for outlets collected on an annual basis. Data for schools and institutions collected in October; Data for Summer Camps collected for July.

CNP REAUTHORIZATION

Mr. DURBIN. What is the status of the CNP reauthorization?

Mr. LUGWIG. Last year, the House Education and Labor Committee held one hearing on Child Nutrition Reauthorization; the Senate Agriculture Committee just recently held its first reauthorization hearing on March 1, 1994. I understand that we may be heading for early authorizing committee markups some time in May.

Mr. DURBIN. What recommendations have been made regarding changes in child nutrition programs?

Mr. LUGWIG. At this stage, we have not finished evaluating all of the Child Nutrition reauthorization bills and, therefore, have not taken an official position on any of the various bills that have been introduced.

WIC DYNAMICS STUDY

Mr. DURBIN. Mr. Braley told the Committee last year that the Food and Nutrition Service, FNS, was sponsoring a study, the WIC Dynamics Study, to determine the effects of recent WIC participation increases on WIC local agency operations. The study is to provide information about the measures that need to be taken by State and local WIC agencies to accommodate caseload increases. The study will also provide information about the capacity of local health care delivery systems to accept increased referrals of WIC participants for maternal and child health services. The final report was expected to be released by the second quarter of fiscal year 1994. We are almost at the end of that second quarter. When will we receive this report? It would be helpful if we could have this information prior to markup on the fiscal year 1995 bill.

Mr. LUGWIG. The Food and Nutrition Service (FNS) is in the process of reviewing the draft final report on the WIC Dynamics Study. We expect to complete the final report and publish it by June 30, 1994.

REVISED WIC REGULATIONS

Mr. DURBIN. Last year the Committee included appropriation language that allowed the Secretary to waive a 15 percent cap regulation until revised allocation regulations could be issued. What is the status of these revised regulations.

Mr. LUGWIG. The Department published a final rule on October 4, 1993 which removed the provision limiting any WIC State agency to a 15 percent increase in food funding. The change will ensure that all funds appropriated for Fiscal Year 1994 and subsequent years are allocated to State agencies most in need.

The Department is currently developing a proposed rule that considers further changes to the entire food funding formula and we intend to have this rule in effect for Fiscal Year 1995 grant allocations.

WIC NUTRITION EDUCATION

Mr. DURBIN. Please tell the Committee how much of the total appropriation for WIC was spent on providing nutrition education services to recipients for fiscal years 1993 and 1994 and how much you expect to spend in fiscal year 1995.

Mr. LUGWIG. Actual State agency expenditures on nutrition education services are reported annually and is not yet available for Fiscal Years 1993 and 1994. However, State agencies are required to spend one-sixth or 16.7% of their nutrition services and administrative, NSA, grant on nutrition education. Typically, State agencies spend more on nutrition education. In Fiscal Year 1992, 22.32 percent of NSA funds were expended for nutrition education. I will submit for the record what is required to be spent nationally on nutrition education, based on projected funding levels.

[The information follows:]

Fiscal year:

1993	\$121,701,091
1994	141,899,708
1995	155,273,382

WIC REAUTHORIZATION

Mr. DURBIN. The WIC Program is up for reauthorization this year. What recommendations has the Department made to the authorizing Committee?

Mr. LUGWIG. You know the Special Supplemental Food Program for Women, Infants, and Children (WIC) has our full support for reauthorization, and we are 100 percent behind the President's call for full funding for WIC by Fiscal Year 1996. We are still looking into what recommendations we will make to the authorizing committees for all the Child Nutrition Programs, including WIC.

UNSPENT/SPENDFORWARD FUNDS

Mr. DURBIN. Please update the tables that appear on page 272 of last year's hearing record showing the total amount of spendforward funds and the amount of unspent funds that were recovered and reallocated to include fiscal years 1992 and 1993 actuals and fiscal year 1994 estimates.

Mr. LUDWIG. I will submit the information for the record.

[The information follows:]

U.S. DEPARTMENT OF AGRICULTURE FOOD AND NUTRITION SERVICE: SPECIAL SUPPLEMENTAL FOOD PROGRAM FOR WOMEN, INFANTS, AND CHILDREN [WIC]

Fiscal year	Total unspent funds	Spendforward funds	Total	Total as percent of appropriation
1982	\$68,962,000	\$68,962,000	7.63
1983	54,969,000	54,969,000	4.74
1984	27,022,000	27,022,000	1.99
1985	36,489,000	36,489,000	2.43
1986	34,040,000	34,040,000	2.15

U.S. DEPARTMENT OF AGRICULTURE FOOD AND NUTRITION SERVICE: SPECIAL SUPPLEMENTAL
FOOD PROGRAM FOR WOMEN, INFANTS, AND CHILDREN [WIC]—Continued

Fiscal year	Total unspent funds	Spendforward funds	Total	Total as percent of appropriation
1987 ¹	11,808,000	² +\$7,322,438	19,130,438	1.15
1988 ¹	9,252,000	18,893,644	28,145,644	1.56
1989 ¹	25,608,000	24,997,867	50,605,867	2.62
1990 ¹	28,072,000	26,646,077	54,718,077	2.57
1991 ¹	73,382,000	27,429,625	100,811,625	4.29
1992 ¹	66,232,294	34,662,544	100,894,838	3.88
1993 ³	120,000,000		120,000,000	4.20
1994 ³	120,000,000		120,000,000	3.74

¹ Figures are net of spendforward amounts.

² Increase due to statutory provision enacted by Congress to allow States to accommodate the significant savings achieved through infant formula rebates.

³ Estimate, includes spendforward amounts.

BREASTFEEDING FOOD PACKAGE

Mr. DURBIN. You are now offering a specially designed food package for mothers in the WIC Program who agree to breastfeed their babies. How many States have chosen to offer this new food package? What effect has this new food package had on the incidence of breastfeeding in the program?

Mr. LUDWIG. The final rule which allows State agencies to offer the Enhanced Breastfeeding Food Package was published in the *Federal Register* on November 27, 1992. State agencies could implement this new food package immediately after the final rule was published. However, State agencies had up to one year after the publication date to implement the new food package.

Currently, all Special Supplemental Food Program for Women, Infants, and Children agencies are providing the enhanced breastfeeding food package to those breastfeeding WIC mothers who choose not to receive infant formula from the WIC Program.

Food Package VII provides increased amounts of juice, cheese, and legumes and two new items: canned tuna fish and carrots.

Because the new food package was so recently implemented, the Food and Nutrition Services does not yet have data on the effects of this new food package on the incidence of breastfeeding in the WIC Program. Such effects would be difficult to isolate from other ongoing promotional efforts. Further, it was not the Department's intent to use this food package primarily as an incentive to breastfeed. Rather, the primary purpose of the new package is to meet the increased nutrient and caloric needs of breastfeeding mothers. Of course, the package does reduce the disincentive to breastfeed reportedly perceived by some recipients. Apparently, they felt they lost the free formula if they breastfed, and this package may appear to even up the benefits.

The Department strongly supports any and all State agency efforts to evaluate the effect of this food package. However, we do not intend to create additional reporting burdens by requiring States to conduct routine evaluations of Food Package VII. The Department may explore the use of this food package as an optional component of the WIC Nutrition Education Assessment Study, currently underway.

LOW-FAT FOODS IN WIC FOOD PACKAGES

Mr. DURBIN. Some of the authorized supplemental foods in the WIC food package are milk, cheese, eggs, and peanut butter. These foods are relatively high in fat and cholesterol content. Are lower fat versions of these foods such as skim milk and low-fat cheese prescribed?

Mr. LUDWIG. Yes. Federal regulations governing the WIC food packages have historically allowed the following range of milks: fresh fluid whole; lowfat, skim and cultured butter milks, evaporated whole or skimmed milks; and dry whole, lowfat or nonfat milks. A number of lactose-reduced and lactose-free lowfat milks, recently introduced on the market, also meet the Federal requirements for eligible WIC milks. In addition, the Department has reviewed and approved several brands of lowfat, low cholesterol and low sodium cheeses.

These lower fat WIC milk and cheese options are typically made available to WIC women and children by WIC agencies. The American Academy of Pediatrics and other nutrition authorities recommend that reduced fat milks not be given to children under the age of 2. Whole milk and regular cheese may also be desirable for underweight women and children, whereas overweight women and older children may benefit from lower fat selections.

With regard to lowfat peanut butters, the Department is currently consulting with the Food and Drug Administration (FDA) about this issue before making a determination if they are WIC eligible. Our main concern is that there is currently no FDA Standard of Identity for lowfat peanut butters; therefore, the nutritional quality of such products may be lower than regular peanut butter and may vary by brand. Compared to regular peanut butters, lowfat peanut butters may contain a lower percentage of peanuts, an important source of protein which is one of the WIC target nutrients. We are in the process of obtaining more information about the different brands of lowfat peanut butters now on the market to see how they compare in nutritional value to traditional peanut butters. Based upon our findings and FDA advice, the Department will make a decision about the appropriateness of lowfat peanut butters for use in the WIC Program.

BREASTFEEDING PROMOTION ACT OF 1992

Mr. DURBIN. The Breastfeeding Promotion Act of 1992 authorized the Secretary to implement a campaign to promote breastfeeding as the best method of infant feeding and foster wider acceptance of breastfeeding in the United States. The Act also authorized the Secretary to solicit funds from private sources to implement the campaign. What is the status of this initiative?

Mr. LUDWIG. Preliminary planning, incorporating input from experts and the Breastfeeding Promotion Consortium, has been completed for a national breastfeeding promotion campaign, including a needs assessment, workplan, timeline and budget. Because no funds are appropriated to USDA to take on this initiative, the Department is currently exploring private and public sector funding options. No additional funds are requested by the Department, nor

were they envisioned when the legislation was drafted and submitted to the Congress.

BABY FRIENDLY INITIATIVE

Mr. DURBIN. The Department provided \$25,000 to the Department of Health and Human Services in partial support of a grant to study the feasibility of implementing a Baby Friendly Initiative in the U.S. For the record, would you please describe this initiative in further detail and tell us what the results of the study were.

Mr. LUDWIG. The Maternal and Child Health Bureau, DHHS, awarded a grant to the Healthy Mothers, Healthy Babies Coalition to conduct a feasibility study on the Baby Friendly Hospital Initiative, BFHI, to determine how the BFHI could be adapted for use in the U.S. As part of the feasibility study an Expert Work Group was organized to discuss the type of recognition process or accreditation program that should be implemented for U.S. hospitals that are baby friendly. The deadline for completion of the study is June 1994.

FARMERS MARKET COUPON PROGRAM

Mr. DURBIN. In fiscal year 1994 the appropriation for the Farmers Market Coupon program was increased from \$3.0 million to \$5.5 million. This increase allowed new States to be added to the program. For the record, please list those States that were already in the program prior to fiscal year 1994 and those States that were added to the program as a result of the increased appropriation.

Mr. LUDWIG. The following State agencies participated in the WIC Farmers' Market Nutrition Program prior to Fiscal Year 1994: Connecticut, Iowa, Maryland, Massachusetts, Michigan, New York, North Carolina, Pennsylvania, Texas, Washington, and Vermont. As a result of the increase in the Fiscal Year 1994 appropriation, 15 States agencies have submitted State Plans for approval to initiate the Program. We anticipate that we will be able to fund all of the approved State plans, however reductions to the amount of funds requested may be necessary. The 15 States agencies are: California, Cherokee Nation of Oklahoma, District of Columbia, Indiana, Kentucky, Maine, Minnesota, Missouri, New Hampshire, New Jersey, New Mexico, Ohio, Rhode Island, South Carolina, and West Virginia.

COST CONTAINMENT IN WIC

Mr. DURBIN. The Vice President's Task Force Report on the National Performance Review recommended States seek additional savings through better food packages and brand name management practices. Would you describe these two initiatives in further detail. What are you doing, if anything, to implement these recommendations?

Mr. DURBIN. The Vice President's Task Force Report on the National Performance Review encouraged better food management practices and facilitation of multi-State contracts for infant food and formula cost containment in the Special Supplemental Food Program for Women, Infants, and Children (WIC). We have and

will continue to work with WIC State agencies to obtain rebates and achieve other savings in WIC food costs.

States have adopted better food management practices. In an effort to achieve food cost savings, many State agencies require economic package sizes, and encourage or require generic or store brands, and have eliminated high-cost foods from their authorized food list. Several States have extended rebate contracts to other WIC foods. Four States have entered into contracts to receive rebates on infant cereals. In addition to these four, California and Nevada have a joint contract for infant cereal rebates. Maryland, Virginia, and the District of Columbia have entered a joint contract for both infant cereal and infant juice rebates.

We will continue to explore other cost containment initiatives that may provide additional food cost savings to the WIC Program. The Food and Nutrition Service regional offices may provide discretionary nutrition services and administrative funds to support new and promising cost containment projects as well. We do not know if we can achieve the full \$500 million in cost savings envisioned in the report. However, we regard cost containment in WIC as one of our highest priorities in order to achieve full participation of WIC eligibles within the spending targets set by the President.

WIC VENDOR MANAGEMENT

Mr. DURBIN. A final rule addressing WIC vendor management deficiencies outlined in a fiscal year 1988 Office of the Inspector General audit is expected to be published during calendar year 1994. What is the status of this rule?

Mr. LUDWIG. The proposed rule addressing WIC Program vendor management is in clearance within the Department. We expect to publish the rule for comment this summer.

Mr. DURBIN. Why has it taken since fiscal year 1988 to address this issue?

Mr. LUDWIG. After the Office of Inspector General (OIG) audit in 1988 revealed a disturbing degree of abuse among selected food vendors, revisions to the current vendor management regulations were proposed in December 1990. Because of adverse reaction to the prescriptive nature of the proposed rule, the Department revised the rule. The revised rule was resubmitted for formal clearance, but publication was delayed due to the previous Administration's moratorium on new discretionary rulemakings.

In the time since the moratorium was lifted, various vendor related issues and challenges have given rise to further refinements of the proposed vendor management regulations. These refinements are now completed and the revised rule is again in formal clearance. The Department expects the revised proposal to be published for public comment in the summer of 1994.

The revised proposed represents a compromise between the prescriptive style of the original December 1990 rule and the department's concern for instituting some needed standards of vendor management. The rule will afford WIC State agencies flexibility in establishing State-appropriate procedures, while setting standards that reduce vendor abuse.

Areas that the major provisions of the revised proposal address will be submitted for the record.

[The information follows:]

Vendor Selection: Minimum mandatory criteria, which can be expanded by the State, to use in selecting vendors to be authorized.

Vendor Training: Minimum mandatory criteria, which can be expanded by the State, to educate vendors on program requirements and regulations.

Mandatory Minimum High-Risk Criteria: Minimum mandatory criteria, which can be expanded by the State, to use in identifying high-risk vendors.

Vendor Monitorings: State agencies must conduct a minimum specified level of compliance buys on all of their vendors, starting with high-risk vendors.

Vendor Sanctions: Uniform periods of disqualification will be required for certain types of program violations and abuse, based on severity and number of occurrences.

Mr. DURBIN. A study was conducted in the spring of 1993 to investigate the magnitude and incidence of vendor overcharging or undercharging on safe buys. Safe buys are defined as ones in which the purchaser buys all of the food specified on the WIC food voucher. The results, extrapolated to the retail vendor population from which the sample was drawn, suggests that approximately 22 percent of vendors overcharge for WIC foods on one or more of three safe buys. What can be done or what is being done to reduce the incidence of vendors overcharging the system?

Mr. LUDWIG. State agency high-risk vendor detection systems capture information on vendors that have suspicious redemption patterns. States use the information to target vendors for investigation and report annually to FNS on the outcome of those investigations through the Vendor Activity Monitoring Profile, VAMP, report. VAMP, which was implemented by FNS in 1989, captures information on each vendor that was investigated and provides a mechanism for monitoring State agency success in eliminating vendors that overcharge from the Program. To improve State agency abilities to reduce the incidence of overcharging in the Program, FNS will issue proposed food delivery regulations that will substantially strengthen vendor management, including standard penalties for vendors that overcharge and commit other abuses. We anticipate that the proposed regulations will be issued for public comment this summer.

The WIC Vendor Issues Study, which found that approximately 22 percent of the retail WIC vendor population overcharged for WIC foods on one or more of three safe buys, also estimated the aggregate loss due to overcharging to be about \$39.5 million, or 1.9 percent of estimated annual retail redemptions. While this concerns us, it is substantially less than had been anticipated based upon prior studies of smaller scale which used a different methodological approach. Overcharging was found to be more common among stores with less than six registers and when purchases were done with women and child food instruments. Undercharging occurred at a high enough level, \$11.7 million or 0.6 percent of annual retail redemptions; an amount equivalent to 39 percent of the estimated dollars overcharged, that it may be more than a random event, but analyses did not show any significant explanation for undercharging. Overall, the study suggests that the funds loss to the WIC program due to overcharging on safe buys may not be as great as originally believed. However, the finding of a low percentage of funds loss due to overcharging on safe buys cannot be extrapolated to the total amount of fraud and abuse occurring in the WIC program. For example, problems are also likely to exist when

the recipient does not want all of the items the WIC voucher allows them to buy. Also, the abuse related to trafficking is unknown. The food delivery regulations being developed by FNS will address a broad spectrum of issues beyond overcharging on safe buys in order to improve overall WIC vendor management.

WIC INFLATION INDEX

Mr. DURBIN. Report language accompanying the fiscal year 1991 appropriation bill directed the Department to develop an inflation index for use in adjusting the WIC allocations based on foods prescribed in the WIC food package rather than the Thrifty Food Plan. During fiscal year 1993, the Department reviewed all comments received from the public, performed additional tests on the WIC index, and began developing the final report. When can we expect that this final report will be sent to Congress?

Mr. LUDWIG. The report, *An Examination of an Alternative WIC Food Cost Inflation Index*, was sent to Congress in early March 1994.

The Thrifty Food Plan, TFP, projections currently used in the Special Supplemental Food Program for Women, Infants, and Children funding formula are not accurate forecasts of WIC food cost inflation in that, generally, they are higher than actual WIC food cost inflation. However, test results indicated that the WIC index does not accurately project WIC food cost inflation and that the TFP projections predict WIC food cost inflation with a smaller margin of error. Because the WIC index is not an improvement over the current method of projecting WIC food cost inflation, USDA recommended that the TFP projections continue to be used as the inflation adjustment in the WIC funding formula.

The USDA found that appropriate data needed to improve the WIC index was not available. Therefore, the decision was made to expend no additional resources to further develop the WIC index at this time.

I will submit a copy of the report for the record.

[CLERK'S NOTE.—The report is too lengthy for reprint. A copy is retained in Committee files.]

WIC COMPARATIVE ANALYSES

Mr. DURBIN. What were the results of the comparative analyses of WIC participants and non-participants health care use, breastfeeding patterns, and birth outcomes?

Mr. LUDWIG. Between 1989 and 1993, the Food and Nutrition Service conducted and published several analyses based on linked 1988 Women, Infants and Children (WIC), Medicaid, and Vital Records data from five states. In these analyses, researchers compared health care costs, health care use, and birth outcomes among Medicaid-eligible women who participated in WIC during their pregnancies, and Medicaid-eligible women who did not participate in WIC. The principal findings of the WIC Medicaid analyses will be submitted for the record.

[The information follows:]

HEALTH CARE USE

Medicaid-eligible women who participated in WIC during pregnancy were more likely to receive adequate prenatal care than those who did not participate in WIC. In these analyses, the definition of adequacy takes into account both the timing of entry into prenatal care (relative to the start of pregnancy), and the number of prenatal visits, adjusted for the length of gestation.

Medicaid costs for women and their infants in the first 60 days postpartum were significantly lower for women who had participated in WIC during pregnancy. Estimated benefit-cost ratios ranged from 1.77 in Florida to 3.13 in North Carolina, indicating that every dollar spent on the prenatal WIC program saved between \$1.77 and \$3.13 in Medicaid costs from birth through 60 days. These estimated savings were independent of the receipt of prenatal care.

BIRTH OUTCOMES

Among Medicaid-eligible pregnant women, participation in WIC was also associated with higher average infant birthweights, longer average gestations, fewer preterm births, and lower infant mortality rates.

Because of lower Medicaid eligibility limits in 1988, all women in the study, both WIC and non-WIC, were significantly more disadvantaged than the overall WIC and Medicaid populations today, and all were well below the 1988 Federal poverty income guidelines.

BREASTFEEDING

Most of the breastfeeding data currently available to FNS are from the livebirth sample of the 1988 National Maternal and Infant Health Survey (NMIHS), a nationally representative survey of live births in 1988. FNS published an analysis of breastfeeding initiation and duration among WIC participants and income-eligible non-participants in 1992.

Descriptive analyses of these data found that WIC participants were significantly less likely to initiate breastfeeding than income-eligible non-participants. However, the two groups had comparable rates of breastfeeding initiation when the findings were adjusted using multivariate techniques to take into account inter-group differences in maternal age, income, education, ethnicity, and other unmeasured characteristics that are associated with breastfeeding, but are independent of participation in WIC.

Factors associated with the duration of breastfeeding, include maternal age, ethnicity, location of residence, and living situation. However, participation in WIC was not a factor associated with the length of time women chose to breastfeed.

WIC STUDIES

Mr. DURBIN. Please describe in further detail the Services Integration Study and the WIC Infant Feeding Practices Study. What is the need for these studies? What impact will they have on the program?

Mr. LUDWIG. The objectives of the Services Integration Study are: to describe low-income women's participation in Federal, State, and private assistance programs (such as, Aid to Families with Dependent Children (AFDC), Food Stamps, Head Start, Medicaid, Maternal and Child Health (MCH) Services Block Grant, Special Supplemental Food Program for Women, Infants, and Children (WIC), private physicians); to describe women's patterns of participation; to describe the intake and referral processes and other program characteristics; to determine women's reasons for not entering programs they knew about and entering programs late in pregnancy; and to determine if there is a relationship between characteristics of the service network, such as method of intake and referral, and the likelihood that a pregnant woman obtains all needed benefits and the trimester of enrollment in programs.

The Services Integration Study will have three parts. First, a survey of local service providers will describe service networks op-

erating within communities served by a sample of 30 WIC agencies. Second, a retrospective survey of mothers whose infants are certified to receive WIC benefits will investigate the mother's participation in assistance programs.

The Services Integration Study is needed because policy makers do not have an overview of the services that low-income pregnant women receive that takes into account when they enroll and how steadily they participate. The study will provide this overview. In addition, because one goal of WIC is to increase participants' regular use of health care, this study will determine the extent to which this occurs. It will also describe the prenatal services received by women who enroll their infants in WIC, but were not themselves in WIC while pregnant. These are women who may have been in the public health system, but not WIC. Questions to be addressed in the study include "Did these women receive other care during pregnancy?" and "Were they income-eligible for WIC?"

The overall goal of the WIC Infant Feeding Practices Study is to address the lack of information about infant feeding practices among WIC participants. The study will describe infant feeding practices among WIC participants by examining pre- and post-natal influences on infant feeding practices among WIC participants and describing the manner in which foods in the WIC package are being used. In addition, it will identify attitudes and practices of WIC participants relative to the initiation and continuation of breastfeeding including identifying potential barriers to the initiation and continuation of breastfeeding.

The WIC Infant Feeding Practices Study will use a series of questionnaires developed by the Food and Drug Administration that will be modified to meet the information needs of FNS and to be administered by telephone. Data will be collected ten times over a period of a year.

This study is needed because very limited and inadequate data are available on the timing of the introduction of various foods into the infant diet or on the total diet of infants at various stages of life during their first year. Similarly, little is known of how infant formulas are selected, purchased, and used, or how or when decisions are made to introduce or withdraw various supplements and foods. The results of this study will be used to: determine the use of food included in the WIC food package, target nutrition education concerning appropriate infant feeding practices, and monitor the national breastfeeding campaign and the *Healthy Children 2000* objectives.

INFANT FORMULA ANTITRUST CHARGES

Mr. DURBIN. The Federal Trade Commission filed antitrust charges against three infant formula companies for violating the law in Puerto Rico. Two of the companies, Mead Johnson and Wyeth, entered into a consent decree to provide 3.6 million pounds of infant formula powder or its equivalent in liquid concentrate valued at \$25 million to the program. The third company, Ross Laboratories, had not yet settled at the time of last year's hearing. What is the status of this case?

Mr. LUDWIG. The court hearing is in process; the judge has not completed deliberations.

INFANT FORMULA REBATES

Mr. DURBIN. Please update the table that appears on page 201 of last year's hearing record showing the amount of infant formula rebate revenues and the number of participants supported by this amount to include fiscal year 1992 actuals and estimates for fiscal year 1993.

Mr. LUDWIG. I will provide the rebate savings collected by each WIC State agency in Fiscal Year 1992 for the record, however, the Department does not collect data on the number of participants supported by rebates for each individual WIC State agency. The national estimated rebate savings for Fiscal Year 1993 is \$820 million. The national estimates of participants supported by these rebate savings are 1.2 million for Fiscal Year 1992 and 1.3 million for Fiscal Year 1993.

[The information follows:]

Total rebate savings fiscal year 1992

State agency:

NERO:

Connecticut	\$6,420,093
Maine	2,331,784
Massachusetts	11,460,348
New Hampshire	1,721,507
New York	58,971,944
Rhode Island	2,473,435
Vermont	0
Indian Township	0
Pleasant Point	0
Seneca Nation	8,615
Subtotal	<u>83,387,726</u>

MARO:

Delaware	2,056,925
District of Columbia	3,323,086
Maryland	12,842,053
New Jersey	16,041,530
Pennsylvania	30,765,596
Puerto Rico	9,439,801
Virginia	13,073,311
Virgin Islands	315,825
West Virginia	3,730,761
Subtotal	<u>91,588,888</u>

SERO:

Alabama	16,866,032
Florida	44,315,755
Georgia	26,776,965
Kentucky	10,658,300
Mississippi	0
North Carolina	23,441,397
South Carolina	5,740,743
Tennessee	21,741,722
Seminoles	0
Miccosoukee	0
Choctaw	0
East Cherokee	20,697
Subtotal	<u>149,561,611</u>

MWRO:

Illinois	28,594,075
Indiana	15,233,397

Michigan	31,207,014
Minnesota	10,198,071
Ohio	23,412,390
Wisconsin	10,557,162
Subtotal	<u>119,202,109</u>

WRO:

Arkansas	11,108,116
Lousiana	14,323,061
New Mexico	5,666,100
Oklahoma	8,211,285
Texas	68,743,707
ACL, NM	0
8N Pueblo	0
Isleta	0
Santo Domingo	0
5 Sandoval	14,562
San Felipe	0
WCD, Ent	136,713
Choctaw	158,879
Cherokee	619,994
Chickasaw	118,580
Otoe-Miss	41,753
Potawatawi	82,958
Zuni	39,829
ITC, OK	23,039
Subtotal	<u>109,288,576</u>

MPRO:

Colorado	5,676,332
Iowa	4,610,792
Kansas	5,614,829
Missouri	15,384,496
Montana	1,165,666
Nebraska	3,566,890
North Dakota	1,528,221
South Dakota	1,577,807
Utah	994,048
Wyoming	709,544
Shosh/Ara	34,340
Ute Mtn	9,465
Winnebago	30,241
Cheyenne	33,638
Rosebud	67,046
Standing Rock	40,442
Fort Berthold	25,890
Subtotal	<u>41,069,687</u>

WRO:

Alaska	1,280,632
Arizona	9,088,698
California	128,066,231
Guam	291,594
Hawaii	2,730,278
Idaho	1,178,038
Nevada	1,893,403
Oregon	5,277,614
Washington	9,936,365
ITCN	0
Maniilaq	0
Navajos	1,138,381
ITCA	44,706
Subtotal	<u>160,925,940</u>
National	<u>755,024,537</u>

COST CONTAINMENT EFFORTS

Mr. DURBIN. Last year Mr. Braley stated that four WIC State agencies, Indiana, North Carolina, Texas, and New York, had contracted for rebates for infant cereal. He also stated that California was soliciting for an infant cereal rebate. What is the status of each of these efforts? Have any other state agencies contracted for rebates on commodities other than infant formula?

Mr. LUDWIG. The U.S. Department of Agriculture, Food and Nutrition Service (FNS) continues to encourage and promote the purchase of supplemental foods other than infant formula under cost containment procedures. Currently, Indiana, North Carolina, Texas, and New York continue to receive rebates for infant cereal. In addition, California and Nevada are involved in a joint contract for rebates for infant cereal. The Mid-Atlantic FNS region has a tri-State contract for infant cereal and infant juice which involves the District of Columbia, Maryland and West Virginia.

With the enactment of P.L. 102-512, The WIC Infant Formula Procurement Act of 1992, the Secretary is charged with encouraging and promoting the purchase of supplemental foods other than infant formula under cost containment procedures to reduce the costs of any supplemental foods. Also, the Secretary shall inform State agencies of the benefits of cost containment and provide assistance and technical advice at State agency request regarding the State's use of cost containment procedures. FNS is currently meeting this mandate, and will continue to explore other cost containment initiatives that may provide additional food cost savings to the WIC Program. This includes the use of discretionary nutrition services and administrative funds to support new and promising cost containment projects.

INFANT FORMULA PROCUREMENT ACT

Mr. DURBIN. The Infant Formula Procurement Act requires the Department to solicit bids on behalf of a group of States, if requested to do so. Have you acted on behalf of a group of States? What impact has this Act had on your agency?

Mr. LUDWIG. On October 28, 1993, the Food and Nutrition Service (FNS) made an official offer to all WIC State agencies to conduct bid solicitation and selection for infant formula rebates on their behalf. In addition, the draft Request for Rebates (RFR) was provided to State agencies for their review and comments. As a result of FNS' offer, seven State agencies expressed an interest in participating in the national bid solicitation. The seven State agencies in the bid group include four Northeastern States and three Indian Tribal State agencies. The RFR was finalized and sent to interested State agencies on March 15, 1994. The current contracts of the States in the existing bid group expire on September 30, 1994; therefore, the effective date of the national contract will be October 1, 1994.

Regarding Agency impact, this Act is fairly labor-intensive for USDA as well as States. However, it is too early to determine whether a national bid solicitation will prove to be more cost-effective than that which could be achieved by individual State solicitation.

OPERATION WEED AND SEED

Mr. DURBIN. Operation Weed and Seed was an initiative to promote neighborhood revitalization in designated cities. Is this still an ongoing program? If so, is WIC still a player in the program?

Mr. LUDWIG. Operation Weed and Seed is an active operation in selected sites throughout the Nation. The WIC program has provided, and continues to provide, active support and assistance to the Weed and Seed communities. USDA has encouraged WIC State agencies to provide as much technical support and assistance as possible to the sites. In some instances, WIC State agencies have redirected additional caseload to the sites to allow greater program access to these especially needy areas. Some States have positioned WIC Farmers Market Nutrition Programs so that they are especially accessible to WIC participants in the Weed and Seed neighborhoods. Several locations have benefited from receipt of WIC discretionary funds to do special outreach projects. As an adjunct to health care, WIC is a particularly important program for the Weed and Seed sites.

EMPOWERMENT ZONES

Mr. DURBIN. The Secretary has a similar initiative to enhance rural communities through the establishment of three rural empowerment zones and 30 rural enterprise communities. Will the WIC Program or any of the Food and Nutrition Programs be involved in this initiative? If so, tell us the funding level for each program that will be devoted to each zone.

Mr. LUDWIG. The Empowerment Zones and Enterprise Communities program is similar to Weed and Seed in that it is intended to assist distressed urban and rural communities achieve self-sufficiency through innovative and comprehensive strategic plans developed and implemented by alliances among private, public, and non-profit entities at the community level. USDA is charged with the management of the rural community programs under this initiative. At this time, notices of interest are being received from communities by USDA; all applications are due by the end of June. Interested communities are currently developing strategic plans. As with the Weed and Seed effort, Food and Nutrition Service programs can be very important forces in local strategic plans. For example, special outreach efforts can assure that eligibles are reached with Food Stamps, free and reduced priced meals, commodities and WIC. Several of these programs have discretionary funds for special demonstration projects which might be useful to the selected communities. For example, WIC discretionary funds might be available for special coordination projects such as the delivery of WIC services to pregnant teenagers in school, or to conduct special outreach or nutrition education efforts, as was done for Weed and Seed neighborhoods. The Food and Nutrition Service will be working with the Rural Development Agency of USDA to promote the incorporation of the domestic food assistance programs into local community strategic plans. Since the zones are not yet selected, we are unable to indicate the nature and level of support provided to this effort by the Food and Nutrition Service programs.

WIC STUDIES

Mr. DURBIN. Please update the list of all ongoing and planned WIC studies to include new studies initiated in fiscal year 1993, additional studies planned for fiscal year 1994, and results of any studies that were completed.

Mr. LUDWIG. I will include for the record the status of those studies that were in progress in Fiscal Year 1993 as well as the new Special Supplemental Food Program for Women, Infants, and Children (WIC) studies to be initiated in Fiscal Year 1994.

[The information follows:]

Ongoing WIC Program Studies

NATIONAL MATERNAL & INFANT HEALTH SURVEY (1990 FOLLOW-UP)

The Food and Nutrition Service (FNS) transferred funds to the National Center for Health Statistics (NCHS) to support this large-scale survey of women and their infants. The survey collected extensive data on medical, behavioral and socioeconomic factors which influence pregnancy and birth outcomes. At FNS's request, questions on WIC participation were included in the survey to increase the usefulness of this rich database for WIC Program analyses. FNS has received a fully documented maternal and provisional health care provider data set. Analyses of the maternal data are currently underway. Follow-up data on the original respondents and their children will be obtained from NCHS in a separate study.

Status: All data sets are expected to be delivered to FNS by Spring 1994.

WIC MODELING AND ANALYTIC PROJECTS (MAP)

This study provides for analyses of extant data bases (such as the National Maternal and Infant Health Survey, the 1990 Longitudinal Follow-up, PC88, and WIC/Medicaid Cost-Benefit Studies). MAP also has essential quick turnaround, ad hoc analysis capability to answer questions posed by legislators and policymakers on the WIC Program. Some research topics include: participant health status characteristics; participation patterns; State-level eligibility estimates; breastfeeding prevalence and duration; infant formula prices and market effects of rebates; and the effect of WIC participation on infant mortality and costs of medical care.

Status: The last report is scheduled for release in 1994.

WIC DYNAMICS

Increased participation brought on by rebates and more funding, along with other changes, have affected the dynamics of WIC local agency operations. This study will describe the effects of such changes on service to participants and on those who operate the WIC Program. Areas of key interest include the impacts on health care referrals and other links to the medical community and the current status of nutrition education. An understanding of challenges to program integrity, opportunities for greater effectiveness, and participant responses to new conditions are necessary for future program planning and budgeting.

Status: The final report is scheduled to be completed in the third quarter of Fiscal Year 1994.

NATIONAL BREASTFEEDING PROMOTION MEDIA CAMPAIGN

The Breastfeeding Promotion Act of 1992 authorized USDA to implement a campaign to promote breastfeeding as the best method of infant feeding and foster wider acceptance of breastfeeding in the United States utilizing funds donated to the United States Department of Agriculture (USDA) by the private sector. The Act also authorized USDA to solicit funds from private sources to implement the campaign. Preliminary planning, incorporating input from experts and the Breastfeeding Promotion Consortium (since June 1990 USDA has hosted two meetings a year of the Consortium), has been completed for a national breastfeeding promotion campaign, including a needs assessment, workplan, timeline and budget.

Status: USDA is seeking funding for the campaign.

WIC PARTICIPANT AND PROGRAM CHARACTERISTICS STUDY - 1992

This biennial study describes WIC participants in April 1992 using information reported to FNS to provide Congress nationally representative data on WIC State Agencies and WIC participants, including income and nutritional risk characteristics, participation by migrant farmworker households, and other attributes of participants the Secretary considers appropriate.

Status: Project is ongoing. The Congressional Report on national summary characteristics is being completed.

WIC ELIGIBILITY STUDY II

This study will review the eligibles estimation methodology and produce estimates of persons eligible for the WIC Program at the national, State and county levels. The estimates will include the Congressionally mandated estimate of income eligible women, infants and children. The study will also analyze new national health and nutrition data from the Third National Health and Nutrition Examination Survey to update information on the portion of income eligible persons likely to be at nutritional risk and thus fully eligible for the WIC Program.

Status: National, State, and county level income eligible data were released in August 1993. Analysis of nutritional data and of potential methods for updating State estimates is underway.

WIC DIETARY ASSESSMENT VALIDATION STUDY

WIC State agencies have been encouraged to use validated dietary assessment procedures that are based on professionally recognized guidelines and to use a food frequency instrument when dietary risk is the only eligibility factor. Two food frequency questionnaires have been developed for use in determining WIC eligibility for women and children. The primary focus of this study is a validation of the food frequency instruments to assess

suitability for certain ethnic groups served by the WIC Program, and accurateness and simplicity of scoring.

Status: A contract was awarded in Fiscal Year 1992. Dietary intake data collection was completed in February 1994. Usability assessment will be completed by April 1994. The entire study and final report are expected to be completed by September 1994.

NUTRITION EDUCATION ASSESSMENT

The purpose of this project is to document the process of nutrition education as it is currently taking place in selected WIC local agencies: to identify factors that may be related to positive nutrition education outcomes; to evaluate the impact of WIC nutrition education on participant knowledge, attitudes, practices and satisfaction with nutrition education; to relate possible changes in these to specific nutrition education formats or inputs; and to identify strategies that are effective in reaching hard-to-serve populations such as low-literacy groups, teenage mothers, and members of different ethnic and cultural groups. The study will collect participant and agency level data on nutrition education impacts in six sites. Additional data on nutrition education processes will be collected in up to 24 additional sites.

Status: The study instrument is currently being finalized. Data collection is expected to begin in July 1994.

STUDY OF WIC PARTICIPANT AND PROGRAM CHARACTERISTICS - 1994

Public Laws 99-500 and 99-591 enacted in 1986 require that FNS submit to Congress a biennial report on WIC participant and program characteristics. To satisfy this requirement, FNS developed a prototype system which will routinely collect WIC Program information directly from WIC State agencies, beginning in 1992. This effort will use the prototype to collect data for April 1994 and April 1996. FNS plans to contract for analysis of the data submitted for 1994 and 1996.

Status: Guidance on submitting data has been provided to WIC State agencies and file testing is underway prior to submitting full WIC caseload files for April 1994.

WIC MODEL APPLICATION FORM

A model application form for use by a pregnant woman or child under the age of 6 for numerous maternal and child assistance programs, such as Medicaid, Head Start, and WIC. An interagency agreement will be used for an evaluation of whether, and to what extent, States adopt and modify the model application form to suit their individual State and local program requirements and needs. In addition, the evaluation will assess the usefulness of the model form for program access and coordination of services.

Status: In Fiscal Year 1993, the Food and Nutrition signed an interagency agreement with and transferred \$100,000 to the Maternal and Child Health Bureau to support a contract to evaluate the use of the Model Application Form. The evaluation is currently underway and is expected to be completed in Fiscal Year 1995.

SERVICES INTEGRATION STUDY

This study will examine the use of services among low-income pregnant and postpartum women whose infants are enrolled in WIC. Services include AFDC and Medicaid. The study will examine the characteristics of women who enroll early, and characteristics of program coordination that promote early enrollment and active participation.

Status: A contract was awarded in Fiscal Year 1993.

STANDARDIZED NUTRITION RISK CRITERIA

In September 1993, FNS awarded a grant in the amount of \$750,000 to the National Academy of Sciences (NAS) to conduct research leading to a consensus report on the nutritional risk criteria currently being used to certify individuals for participation in the WIC Program. There is currently a great deal of variation in the actual nutritional risk criteria used by different State agencies, and in threshold values used to define various levels of risk. FNS has requested that NAS assess the scientific knowledge base underlying each of the nutritional risk criteria, and recommend threshold values for determining who is at risk with respect to each criterion.

Status: The work is expected to last 24 months, from September 1993 to September 1995. NAS will issue its report at the completion of the project.

INFANT FEEDING PRACTICES

This study addresses the lack of information about infant feeding practices among WIC participants. It will include the circumstances and influences that shape maternal intentions regarding feeding practices during the first year of life. Information will be collected before delivery and after delivery periodically for a specified number of months. The study will address issues such as changes in feeding patterns over time, factors that influence feeding patterns, and relationships between feeding patterns and subsequent health of the infant.

Status: A contract was awarded in Fiscal Year 1993.

WIC MODELING AND ANALYTIC PROJECTS (MAP) II

The purpose of this 3-year project is to assess the feasibility of developing microsimulation models for WIC, and to provide up-to-date analyses of policy issues pertaining to the Special Supplemental Food Program for Women, Infants and Children (WIC). The project will entail reviewing and summarizing relevant literature on microsimulation, and exploring practical methods of developing such models for WIC using extant data sets. Each discrete task represents a distinct but related area of WIC policy research or analysis which is expected to have policy significance for WIC over the next 3 years and beyond. Other research topics include variation in referral patterns and length of participation; characteristics of unserved or underserved pregnant women; minority participation; characteristics of pregnant women by trimester of enrollment; variation in nutritional risks; nutritional risk profiles of infants and children enrolled in WIC. The project also has a rapid response component that will enable FNS to respond to inquiries by legislators and policymakers.

Status: Contract negotiations are ongoing.

WYOMING WIC AND FSP SMARTCARD DEMONSTRATION

FNS is evaluating Wyoming's demonstration of a multiple program Electronic Benefit Transfer (EBT) system in Natrona County, Wyoming. Wyoming's Natrona County project will examine the potential for linking the Special Supplemental Food Program for Women, Infants and Children (WIC) and the Food Stamp Program (FSP) from the perspective of program clients, private-sector partners (food retailers, banks, and processors), and State and Federal Program management. Wyoming has contracted with National City Processing Company over an approximate 3-year time frame to have a joint WIC/FSP off-line (smartcard) system designed, developed, tested, and maintained through a pilot period. The five major purposes of the evaluation are: 1) to describe system design, development and operations for Natrona County as compared to the preceding WIC and FSP systems; 2) examine costs to organizations of administering the paper-based issuance for WIC and FSP and the demonstrated EBT system for these programs; 3) assess the effects of the demonstration system on each major stakeholder group; 4) estimate and compare the cost-effectiveness of the demonstration to previous systems; and 5) determine factors necessary to expansion of Wyoming's WIC/FSP smartcard system.

Status: The evaluation extends from September 30, 1993 through April 30, 1996. An Interim Report on EBT system implementation is expected in Fall 1995, with a Final Evaluation Report in Spring 1996. Wyoming's contract for system construction began work in December 1993 and is expected to conduct system tests of the joint WIC and FSP system in Fall 1994.

Completed WIC Program Studies

WIC VENDOR ISSUES STUDY

This study examined the prevalence and magnitude of vendor overcharging in the WIC Program. A national estimate of vendor overcharging was established through compliance buys from a nationally representative sample of WIC vendors. The study found that approximately 22 percent of the retail WIC vendor population overcharged for WIC foods on one or more of three safe buys. The estimated aggregate loss due to this overcharging is about \$39.5 million, or 1.9 percent of estimated annual retail redemptions. This estimate is substantially less than had been anticipated based upon prior studies. Undercharging occurred at a level equivalent to 39 percent of the estimated dollars overcharged. This may be more than a random event, but analyses did not show any significant explanation for undercharging. The estimate of overcharging will serve as a national baseline from which to assess the effectiveness of WIC State agencies' actions in curbing overcharging. This study also examines characteristics of vendors found to be overcharging in the WIC Program.

WYOMING WIC EBT ASSESSMENT

The State of Wyoming pilot tested an off-line "smart card" benefit delivery system from May to December 1991. The test included about 800 WIC participants served out of 4 food retail stores in the Casper area. Due to time constraints, FNS and Wyoming entered into a limited cooperative agreement to gain some insight into effects on each major participating group (i.e., WIC participants, retail vendors, WIC State and local agencies, banks, etc.). A report showing positive attitudes among these stakeholders in regard to their acceptance and ability to use the "smartcard" was shared with FNS under this agreement.

New WIC Program Studies

DEMONSTRATION OF AN ON-LINE WIC/FSP EBT SYSTEM

FNS currently has limited experience with WIC EBT. With the Secretary's call for nationwide EBT by 1996, it is critical that the Agency explores the integration of WIC with on-line EBT systems. This project would partially support the development of an on-line EBT system. An evaluation would establish technical feasibility and compare administrative costs and user group satisfaction of the paper systems with the integrated EBT system.

Status: Contract will be awarded in Fiscal Year 1994.

HEAD START/WIC COOPERATION PROJECT

The WIC/Head Start Coordination Study will identify overlapping areas in the required standards for the WIC and Head Start Programs, particularly in the area of nutrition education. It

will also describe potential areas of coordination between WIC and Head Start and identify barriers to coordination. This project will examine the current efforts of Head Start and WIC Programs in working together at the local level to better serve the needs of low-income parents. Targeted areas will include: nutrition services; nutrition education; staff training; volunteer services; drug abuse prevention information and referrals; immunization screening and referrals; other health care services and referrals (for example, medicaid, EPSDT, dental services); shared information; paraprofessional services; and research. The outcome of this project will be a technical assistance manual which will provide local WIC and Head Start Program staff with information on potential areas of coordination, including specific examples of current successful efforts.

Status: Contract will be awarded in the fourth quarter of Fiscal Year 1994.

WIC FOOD PURCHASING STUDY

The WIC Food Purchasing Study will describe food instrument redemption patterns of WIC participants by category of participants (e.g., which foods are prescribed, which are redeemed, and in what quantities, and which are not) and determine if differences in WIC food instrument redemption patterns exist among various ethnic groups. This study will use two sources of electronic data; primary data will not be collected. First, point-of-sale UPC scanner code data from retail food stores will be used to examine WIC recipient food instrument redemption patterns; the unique food instrument number will be also entered by the retail store cashier at the point of purchase. Second, the unique food instrument number will be used to link retail store scanner data with WIC State agency administrative data in order to obtain information on which foods were prescribed, as well as demographic information.

Status: Contract will be awarded in the fourth quarter of Fiscal Year 1994.

WIC NUTRITION EDUCATION DEMONSTRATION STUDY

This study will (1) examine the effectiveness of current WIC nutrition education in increasing participants' knowledge of nutrition; (2) test the effectiveness of innovative WIC nutrition education in increasing knowledge; and (3) compare participant-cost ratios for current and innovative programs. FNS will examine the effectiveness and costs of current and innovative WIC nutrition education at several local agencies. The information produced by this study will allow the Agency to determine (1) if there are innovative nutrition education programs that do as well as current programs in providing nutrition knowledge to participants; and (2) whether these innovations use fewer resources to produce knowledge gains. This information will

allow FNS to help agencies adapt to resource constraints.

Status: A contract will be awarded during the fourth quarter of Fiscal Year 1994.

NUTRITION MEDIA CAMPAIGN

This project will develop national nutrition education media messages that reach young people with nutrition information that is lively and entertaining.

Status: A contract will be awarded during Fiscal Year 1994.

COMPETITIVE NUTRITION EDUCATION COMMUNITY CHALLENGE GRANTS

Through a competitive award process, FNS will seek five demonstration communities (three urban and two rural) in which an alliance of community partners -- food retailers, food banks, private assistance agencies, media and employers -- make a commitment, in cooperation with government agencies, to identify hunger and dietary problems, develop comprehensive solutions through joint and coordinated efforts, and integrate nutrition education and messages into all alliance contacts with recipients. Other parts of USDA (e.g., Human Nutrition Information Service, Extension Service) and DHHS will be solicited as partners. An independent process evaluation will also be funded to assess factors that lead to alliance success.

Status: A contract will be awarded during Fiscal Year 1994.

BREASTFEEDING PROMOTION

This effort would test the effectiveness of communicating different messages to WIC participants about the initiation and duration of breastfeeding. The project would look at target audiences as well as particular messages. It would examine infant feeding attitudes and practices of various groups to determine target audiences, and develop themes and messages that address key barriers. Commercial market data on media audiences could be examined to identify the most effective channels for disseminating messages.

Status: A contract will be awarded during Fiscal Year 1994.

MODEL APPLICATION FORM

Mr. DURBIN. At this time last year the Department was in the process of developing an interagency agreement with the Maternal and Child Health Bureau of the Department of Health and Human Services to support a jointly funded contract to evaluate the extent to which the States had adopted or adapted for local program use the model application form. What is this status of this agreement?

Mr. LUDWIG. In Fiscal Year 1993, the Food and Nutrition Service signed an interagency agreement with, and transferred \$100,000 to, the Maternal and Child Health Bureau to support a contract to evaluate the use of the Model Application Form. The evaluation is currently underway and is expected to be completed in Fiscal Year 1995.

WIC CULTURAL FOOD PACKAGE

Mr. DURBIN. Also at this time last year, you were developing a Notice of Solicitation of Public Comment to be published in the Federal Register to gather public comments regarding the accommodation of cultural food patterns in the WIC food packages. What is the status of this initiative?

Mr. LUDWIG. The draft has now been completed. It is anticipated that the document will enter formal Departmental clearance shortly, and that the Notice will be published in the *Federal Register* this summer.

In this document, the Department traces the history of cultural accommodation in WIC and presents broadly stated questions for comment. Some questions are focused on ideas for regulatory or policy redirection; others simply are seeking information on better ways to meet needs of a diverse clientele within current requirements. Commenters may also address additional issues which are within the scope of the Notice. Individual WIC State and local agency comments are very important and strongly encouraged, as are comments from the public health nutrition community, industry, and the general public, including those individuals who have been served or are being served by WIC.

NAS STUDY ON NUTRITIONAL RISK CRITERIA

Mr. DURBIN. Last year I asked Mr. Braley if the Department had explored the option of establishing one set of eligibility criteria in the WIC program for all States to follow. He responded that the Department was considering entering into a cooperative agreement with the National Academy of Sciences to conduct a scientific review of the nutritional risk criteria used in the WIC program. Has this cooperative agreement been signed? If so, when can we expect a report from the Academy? If not, why not?

Mr. LUDWIG. In September 1993, the Food and Nutrition Service awarded a grant in the amount of \$750,000 to the National Academy of Sciences, NAS, to conduct research leading to a consensus report on the nutritional risk criteria currently being used to certify individuals for participation in the Supplemental Food Program for Women, Infants, and Children.

There is currently a great deal of variation in the actual nutritional risk criteria used by different State agencies, and in thresh-

old values used to define various levels of risk. FNS has requested that NAS assess the scientific knowledge base underlying each of the nutritional risk criteria currently used in the program, and obtain scientific consensus on these criteria, and values for determining who is at risk with respect to each criterion.

The work is expected to last 24 months, from September 1993 to September 1995. NAS will issue its report at the completion of the project.

WIC ELIGIBILITY AND PARTICIPATION

Mr. DURBIN. Please update the table that appears on page 278 of last year's hearing record showing the WIC eligibility and participation rates to include fiscal years 1992 and 1993.

Mr. LUDWIG. FNS is currently in the process of developing the estimates of WIC eligibility and participation rates for 1992. These estimates will be available later this Spring. Our estimates of eligibles are based primarily on data from the March Current Population Survey, CPS. Because CPS data for 1993 will not be available until late this year, we cannot develop a 1993 estimate at this time.

WIC INCOME ELIGIBLES

Mr. DURBIN. Provide a separate table showing the number of WIC eligibles by State.

Mr. LUDWIG. In August 1993, FNS released State- and county-level estimates of the average monthly number of persons income-eligible for WIC. These estimates have been developed using data from the 1990 Decennial Census of Housing and Population. FNS is currently researching methods for updating the Census-based estimates with reliable annual state-level estimates.

A summary table of income-eligibles by State from the report Estimates of Persons Income Eligible for the Special Supplemental Food Program for Women, Infants and Children (WIC) in 1989 is submitted for the record. The full report has been provided to the Subcommittee. Please note, however, that the numbers are for income eligibles only and do not reflect the fully eligible number once nutrition risk criteria have been applied.

[The information follows:]

SUMMARY - Estimates of the Average Monthly Number of Women, Infants, and Children Income Eligible for the WIC Program in 1994

	Pregnant Women	Postpartum Nonbreastfeeding	Postpartum Breastfeeding	All Women	Infants age < 1	Children age 1-4	All WIC Groups
Alabama	18,406	10,730	4,561	33,659	28,101	107,589	169,360
Alaska	3,302	1,898	895	6,095	5,086	18,471	29,652
Arizona	19,608	10,828	5,074	35,510	29,634	108,391	178,535
Arkansas	11,952	6,852	2,889	21,693	18,122	70,931	110,746
California	132,362	72,145	35,187	239,694	205,688	736,847	1,182,229
Colorado	12,268	7,067	3,283	22,618	19,028	75,211	116,857
Connecticut	6,646	3,778	1,765	12,189	10,255	39,959	62,403
Delaware	1,812	1,048	459	3,319	2,924	11,481	17,724
District of Columbia	3,092	1,688	774	5,554	4,492	13,369	23,415
Florida	47,228	27,015	12,412	86,655	74,065	280,201	440,921
Georgia	29,211	17,014	7,228	53,453	44,675	164,122	262,250
Hawaii	4,311	2,548	1,200	8,059	6,930	24,840	39,829
Idaho	5,009	2,818	1,356	9,283	7,779	30,868	47,930
Illinois	40,297	22,630	10,302	73,229	60,811	231,258	365,298
Indiana	18,457	11,002	4,880	34,339	29,548	116,011	179,898
Iowa	8,986	5,271	2,454	16,711	14,521	56,522	89,754
Kansas	8,976	5,266	2,419	16,661	14,211	57,072	87,844
Kentucky	16,865	9,665	4,133	30,663	25,708	99,224	155,595
Louisiana	25,554	14,154	6,253	45,961	37,443	144,645	228,049
Maine	3,430	2,021	926	6,377	5,682	24,889	36,948
Maryland	11,106	6,451	3,002	20,559	18,473	71,227	110,259
Massachusetts	14,118	7,946	3,789	25,853	21,600	85,685	133,138
Michigan	36,396	21,568	9,620	69,584	57,920	210,556	338,066
Minnesota	12,641	7,245	3,554	23,440	20,372	81,130	124,942
Mississippi	16,945	9,472	3,984	30,401	24,844	92,038	147,283
Missouri	19,451	11,157	4,988	35,596	30,020	117,996	183,612
Montana	3,518	2,014	972	6,504	5,505	22,772	34,781
Nebraska	5,867	3,441	1,654	10,962	9,418	37,248	57,628
Nevada	4,449	2,584	1,203	8,236	7,051	25,830	41,117

SUMMARY - Estimates of the Average Monthly Number of Women, Infants and Children Income Eligible for the WIC Program in 1

	Pregnant Women	Postpartum NonBreastfeeding	Postpartum Breastfeeding	All Women	Infants age 1-4	Children age 1-4	All WIC Groups
New Hampshire	1,950	1,186	555	3,691	3,436	14,601	21,728
New Jersey	16,253	9,288	4,425	29,966	25,609	98,789	154,364
New Mexico	9,953	5,461	2,591	17,995	14,970	55,281	86,246
New York	64,631	35,755	17,273	117,859	97,251	362,426	577,536
North Carolina	25,797	15,268	6,564	47,649	40,643	149,981	238,273
North Dakota	2,720	1,605	762	5,087	4,238	16,678	26,003
Ohio	40,173	22,920	10,238	73,331	61,383	238,351	373,065
Oklahoma	14,554	8,333	3,621	26,508	22,347	86,149	137,004
Oregon	10,751	6,191	2,911	19,853	17,151	65,888	102,892
Pennsylvania	34,664	20,077	9,273	64,014	55,227	220,748	339,989
Rhode Island	2,701	1,545	734	4,980	4,113	16,780	25,873
South Carolina	16,114	9,430	4,055	29,599	24,878	92,301	146,778
South Dakota	3,464	1,934	935	6,333	5,204	21,363	32,800
Tennessee	20,728	11,955	5,089	37,772	31,955	120,112	189,839
Texas	91,738	51,482	23,313	166,533	137,406	520,260	824,199
Utah	8,892	5,309	2,582	16,783	14,346	55,655	86,784
Vermont	1,537	904	450	2,891	2,507	10,738	16,136
Virginia	18,343	10,938	4,893	34,174	29,843	113,321	177,338
Washington	16,745	9,688	4,516	30,949	26,990	104,314	162,253
West Virginia	7,861	4,386	1,869	14,116	11,518	45,639	71,273
Wisconsin	16,083	9,283	4,291	29,657	24,968	101,542	156,167
Wyoming	1,860	1,095	510	3,465	2,877	11,977	18,318
United States (50 States & D.C.)	971,976	551,449	252,876	1,776,101	1,498,766	5,683,277	8,958,144
Puerto Rico	36,976	17,833	7,767	62,576	59,278	209,543	331,397
Virgin Islands	740	362	170	1,272	1,101	4,684	7,057
Guam	868	404	194	1,466	1,402	5,880	8,748
United States (50 States & D.C.) & Puerto Rico, Virgin Islands, & Guam	1,010,560	570,048	260,807	1,841,415	1,560,547	5,903,384	9,305,346

FOLIC ACID

Mr. DURBIN. What are you doing or what have you done with regards to folic acid? I remember last year it was stated that once final recommendations were implemented through a change in the RDA's FNS would consider the impact of those revisions on WIC food packages. What is the status of this issue?

Mr. LUDWIG. The Recommended Dietary Allowances, RDAs, of nutrients established by the National Research Council, National Academy of Sciences, was last revised in 1989. The following values represent the current RDAs for folate for women of childbearing age: 400 micrograms, ug, for pregnant women; 280 ug for breastfeeding women the first 6 months of lactation; 260 ug for breastfeeding women the 2nd 6 months of lactation; 180 ug for nonpregnant women ages 15-51 years; and 150 ug for nonpregnant women ages 11-14 years. However, in September 1992, the U.S. Public Health Service issued a statement recommending that all women of childbearing age consume 400 ug of folate per day to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects.

Early in 1992, the Department completed a formal review of the WIC food packages with the assistance of Pennsylvania State University. This review included an assessment of the nutritional contribution of each of the six WIC food packages, in effect at that time, with regard to the total dietary needs of the different participant categories. Since then, a nutritionally enhanced WIC food package was added for breastfeeding women whose infants are not receiving WIC formula. The review found that when orange juice is selected as the juice provided in the WIC food packages available to all categories of women, pregnant, breastfeeding and postpartum, the food packages provide from 80 percent to more than 100 percent of their RDAs for folate. In addition to orange and pineapple juices, other folate-rich WIC foods include dried beans and peas available to pregnant and breastfeeding women and folate-fortified cereals available to all women. Other WIC foods available that contribute to folate intake are grapefruit juice, eggs and milk which are also available to all women. Further, if a folate-fortified cereal is selected by women participants, all WIC food packages available to them would supply more than 400 ug of folate each day. The WIC food packages are supplemental in nature and not intended to provide for total dietary needs. Nevertheless, all current WIC food packages make substantial contributions to the folate requirements of all women participants.

The Department has plans underway to develop and purchase brochures which address the importance of folate in a woman's diet. These materials will be provided to WIC agencies for use in their nutrition education sessions with all women participants.

THE NATIONAL VOTER REGISTRATION ACT

Mr. DURBIN. Public Law 103-31, the National Voter Registration Act of 1993 requires that all State offices that provide public assistance must distribute mail voter registration application forms and assist applicants in completing the forms unless such assistance is refused. The Act also requires these offices to accept applications

for transmittal to the appropriate State election official. This Act becomes effective on January 1, 1995. What impact will this have on the WIC program?

Mr. LUDWIG. WIC State agencies will need to coordinate implementation of this Act with their State election officials and develop policy on how the provisions of these services will be implemented by WIC offices and incorporated into the WIC application process. By law, WIC offices will need to provide voter registration services at application, reapplication and change of address. Costs associated with implementation of this Act by State agencies will be allowable WIC administrative costs. We are issuing guidance to WIC State agencies to assist them in implementing this Act. In this guidance, we are advising State agencies to integrate the voter registration services in a manner that minimizes burden and is least disruptive to current WIC Program procedures.

BREASTFEEDING PROMOTION

Mr. DURBIN. A recent GAO report on WIC's efforts to promote breastfeeding has recommended that the Secretary direct the Administrator of FNS to improve the dissemination of foreign-language breastfeeding education materials in the program. They also recommended that USDA and DHHS work with State WIC directors to develop written policies defining when breastfeeding is contraindicated. What is being done to implement these recommendations?

Mr. LUDWIG. The Department concurs with the recommendations. Historically, Federal regulations have required WIC State agencies to identify or develop resources and educational materials in languages other than English in areas where needed. This has been further emphasized in a final rule published March 11, 1994. The Department has also traditionally encouraged WIC State/local agencies to utilize the services provided by the Food and Nutrition Information Center, FNIC, which houses such materials. For example, at the USDA-sponsored 1993 National WIC Nutrition Services Conference, attended by over 800 individuals, FNIC conducted a workshop and an exhibit to publicize its services, which consist of the direct loan of books and audiovisuals, free photocopies of journal articles, and comprehensive reference/research services. The conference theme was "Meeting the Needs of a Diverse Population." Development of culturally diverse materials and breastfeeding promotion were also included as part of the 13 plenary/concurrent sessions and workshops.

Through FNS funding, FNIC recently developed a resource guide which contains an annotated bibliography of educational materials in both English and foreign languages, including materials on breastfeeding, available for use in the WIC Program from FNIC. FNS periodically shares information with State directors on new materials available through FNIC.

FNS has just completed a Plan of Action to further carry out this recommendation. The plan includes: reminding WIC State directors about FNIC services; requesting FNS regional directors to consider the provision of discretionary funds for the development of WIC foreign-language materials to appropriate States; and for FNS to consider in its development of Fiscal Year 1996 technical assistance

projects, grants to States for the development of foreign-language materials.

The Department also concurs that it is important that written policy be developed defining when breastfeeding is contraindicated. FNS has included some information on this topic in several of its publications for use in the WIC program. The American Academy of Pediatrics. AAP, in January 1994, revised its 1989 policy statement entitled "Transfer of Drugs and Other Chemicals Into Human Milk," which addresses contraindications to breastfeeding. FNS will be forwarding this statement shortly to its regional offices for dissemination to WIC State agencies. FNS is meeting with DHHS/Maternal and Child Health Bureau staff on May 5, 1994 to discuss the availability of information on contraindications and will work with DHHS on development of policy appropriate for use in the WIC program. WIC policy will conform to that issued by the AAP and DHHS. The science on contraindications to breastfeeding is evolving; FNS will do everything possible to remain in the forefront and share evolving information with the WIC community.

COMMODITY SUPPLEMENTAL FOOD PROGRAM

Mr. DURBIN. As part of the fiscal year 1994 Supplemental and Rescission Bill, Congress rescinded \$10 million of the \$12.6 million that was proposed. This gave the program an additional \$2.6 million in funding for fiscal year 1994 on top of the \$10 million increase provided through the regular appropriation bill. Would you please tell the Committee what amount of funding will be needed in fiscal year 1995 to support the fiscal year 1994 current service level.

Mr. LUDWIG. With the additional \$2.6 million in funding for Fiscal Year 1994, we currently estimate that available funds will support caseload levels of 263,254 Special Supplemental Food Program for Women, Infants, and Children, WIC, type participants and 179,597 elderly participants for the remainder of 1994.

The 1995 Budget request of \$94.5 million will fully support the revised WIC-type caseload in 1995. We estimate that \$15 million will be needed in addition to the 1995 Budget request to maintain revised elderly caseload through 1995.

EXPIRING BALANCE

Mr. DURBIN. The table in the explanatory notes shows a balance of \$2,761,806 expiring at the end of fiscal year 1993. Please explain the reason these funds were not spent.

Mr. LUDWIG. The funds in question were Fiscal Year 1992 monies transferred to Agricultural Stabilization and Conservation Service for the purpose of providing commodities for the Commodity Supplemental Food Program, CSFP. In reconciling of Fiscal Year 1992 accounts, these funds were identified as unspent and returned to FNS. However, because they were returned so late in the fiscal year, we were unable to obligate these funds before the end of Fiscal Year 1993.

FULL FUNDING

Mr. DURBIN. I read in the notes that priority will be given to serving women, infants, and children, consistent with the Administration's emphasis to fully fund nutrition services to this target population. Is it the Administration's goal to fully fund the Commodity Supplemental Food Program as well as the WIC program? If so, what would the cost be to fully fund this program?

Mr. LUDWIG. It is the Administration's goal to fully fund only WIC so that eligible pregnant, postpartum and breastfeeding women, infants and children under age 5 are served. The Administration's estimate for full funding WIC includes maintaining current levels of CSFP participation by WIC eligibles. Otherwise, full funding would cost about \$100 million more. Since CSFP serves essentially the same women, infants, and children who would otherwise be eligible for WIC, CSFP contributes significantly to the overall goal of serving this critical target population and reduces the amount of funding necessary to meet our full funding commitment to WIC.

With regards to CSFP elderly, it is not our goal to fully fund CSFP to reach all eligible elderly participants. The Food Stamp Program is the primary vehicle through which needy elderly are provided with nutrition assistance. Unlike CSFP, the Food Stamp Program is available nationwide.

ORANGE JUICE DONATION

Mr. DURBIN. You state that higher participation is supported in fiscal year 1994, in part, due to a one-time donation of \$4.7 million of orange juice. Would you please explain this one-time donation in further detail, including how many additional participants you were able to add to the program.

Mr. LUDWIG. The Secretary of Agriculture has the authority to stabilize certain commodity markets by purchasing surplus foods when market conditions warrant such intervention. Typically, these purchases are made available for distribution through various food assistance programs.

In fiscal year 1993, the Agricultural Marketing Service, AMS, at the Secretary's direction, made a substantial purchase of fresh oranges, orange juice, and orange juice concentrate. Because orange juice is a component of the authorized CSFP food package, FNS allocated \$4.7 million in orange juice to CSFP to distribute in fiscal year 1993 and fiscal year 1994. The effect of this section was to lower the overall cost of food benefits in the program.

No new caseload was added to CSFP in fiscal year 1993 as a result of this action. The lower food package cost was reflected in caseload allocations for fiscal year 1994 and in the 1994 figures presented in our 1995 Budget request. However, given the fiscal pressures all programs are under, it may not be appropriate to use the one-time availability of donated orange juice to drive program participation to levels that could not be sustained in later years. As I mentioned before, we are reviewing caseload authorizations made earlier for the program to make sure stable operations can be sustained.

Mr. DURBIN. Are these additional participants supported by the fiscal year 1995 budget request?

Mr. LUDWIG. Because orange juice will not be donated to the Commodity Supplemental Food Program (CSFP) in fiscal year 1995, our estimate of food costs in fiscal year 1995 has been adjusted accordingly. In this sense, whatever caseload increase in fiscal year 1994 that might be attributable to orange juice donations will not be sustained in our fiscal year 1995 budget request. And, as you can see, that is why we are taking a close look at this for 1994.

NEW SITES

Mr. DURBIN. Were any new CSFP sites approved in the fiscal year 1994 caseload allocation?

Mr. LUDWIG. The appropriation in fiscal year 1994 did not support the addition of new State agencies. Under current rules, we consider the requests from participating State agencies to expand services before considering requests to initiate a new CSFP site. Since we did not authorize all expansion requests, we were unable to consider new State agencies.

CASELOAD LEVELS

Mr. DURBIN. Please update the tables that appear on pages 283 through 286 of last year's hearing record showing caseload levels to include fiscal year 1993 actuals and fiscal year 1994 requests and authorized levels.

Mr. LUDWIG. Updated charts reflecting actual participation levels for fiscal year 1993, fiscal year 1994 expansion requests, and Fiscal Year 1994 authorized caseload levels will be submitted for the record. There are separate charts for women, infants and children, and elderly.

[The information follows:]

COMMODITY SUPPLEMENTAL FOOD PROGRAM
LOWERS, INFANTS AND CHILDREN CASELOAD

STATES	FISCAL YEAR 1990				FISCAL YEAR 1991				FISCAL YEAR 1992				FISCAL YEAR 1993				FISCAL YEAR 1994			
	STATES' REQUEST FOR	TOTAL AUTHORIZED CASELOAD	EXPANSION CASELOAD	USED	STATES' REQUEST FOR	TOTAL AUTHORIZED CASELOAD	EXPANSION CASELOAD	USED	STATES' REQUEST FOR	TOTAL AUTHORIZED CASELOAD	EXPANSION CASELOAD	USED	STATES' REQUEST FOR	TOTAL AUTHORIZED CASELOAD	EXPANSION CASELOAD	USED	STATES' REQUEST FOR	TOTAL AUTHORIZED CASELOAD	EXPANSION CASELOAD	USED
New Hampshire	1,500	2,342	2,342	0	2,659	12,120	11,120	0	2,327	21,120	21,120	0	2,327	21,120	21,120	0	600	26,120	26,120	0
New York	3,000	6,077	6,063	6,991	12,120	11,120	9,900	0	2,327	21,120	21,120	0	2,327	21,120	21,120	0	1,500	26,120	26,120	0
D.C.	0	5,712	3,360	0	5,569	5,900	1,000	0	5,900	5,900	5,900	0	5,900	5,900	5,900	0	0	5,900	5,900	0
Delaware	0	3,672	3,449	500	3,969	3,366	0	0	3,278	3,278	3,278	0	3,278	3,278	3,278	0	2,700	3,278	3,278	0
Illinois	0	474	564	500	564	564	500	0	564	564	564	0	564	564	564	0	50	564	564	0
Indiana	0	10,403	16,940	3,400	19,940	15,400	0	0	15,400	15,400	15,400	0	15,400	15,400	15,400	0	0	15,400	15,400	0
Iowa	2,466	11,334	10,421	2,466	18,000	12,564	1,336	0	17,000	15,604	15,604	0	1,336	15,604	15,604	0	633	17,000	17,000	0
Michigan	12,000	52,463	48,904	10,000	57,093	57,093	12,075	0	64,312	62,266	62,266	0	6,800	62,266	62,266	0	6,000	64,312	64,312	0
Minnesota	0,212	2,974	2,974	0,212	5,940	5,472	0,212	0	8,906	7,567	7,567	0	7,567	7,567	7,567	0	4,331	8,906	8,906	0
Missouri	46	651	564	0	564	620	0	0	620	607	607	0	607	607	607	0	500	651	651	0
Montana	10,000	29,317	27,060	11,468	35,602	31,592	0	0	31,516	30,436	30,436	0	3,000	30,436	30,436	0	5,000	32,700	32,700	0
Nebraska	0	6,315	6,315	3,465	10,000	10,000	10,000	0	10,000	10,000	10,000	0	10,000	10,000	10,000	0	0	10,000	10,000	0
Nevada	1,950	16,630	16,321	0	16,430	16,321	1,710	0	16,991	16,991	16,991	0	16,991	16,991	16,991	0	2,770	17,171	17,171	0
New Mexico	0	1,672	1,623	0	1,423	1,751	0	0	1,751	1,751	1,751	0	1,751	1,751	1,751	0	0	1,751	1,751	0
New York	3,942	2,751	2,610	5,826	5,261	3,280	2,323	0	4,519	3,045	3,045	0	3,045	3,045	3,045	0	421	3,466	3,466	0
North Dakota	0	6,510	6,100	1,500	7,600	5,127	1,000	0	5,127	4,875	4,875	0	4,875	4,875	4,875	0	700	5,127	5,127	0
Ohio	0	1,232	1,104	0	1,104	927	0	0	927	807	807	0	807	807	807	0	713	1,232	1,232	0
Oklahoma	1,490	6,290	5,840	15,490	12,136	11,136	10,462	0	10,462	10,462	10,462	0	3,000	10,462	10,462	0	0	10,462	10,462	0
Oregon	400	4,907	4,731	0	9,430	9,430	2,000	0	12,130	12,130	12,130	0	5,000	15,490	15,490	0	700	13,440	13,440	0
Texas	0	781	701	276	975	975	256	0	1,225	1,225	1,225	0	1,225	1,225	1,225	0	250	1,440	1,440	0
Tennessee	0	0	0	10,000	0	0	0	0	0	0	0	0	10,000	0	0	0	0	0	0	0
Utah	32,112	0	0	32,112	0	0	32,112	0	32,112	0	0	0	32,112	0	0	0	0	0	0	0
Pennsylvania	0	0	0	3,000	0	0	3,000	0	0	0	0	0	3,000	0	0	0	0	0	0	0
TOTALS	76,321	180,323	169,670	121,256	221,875	209,551	106,161	252,644	243,029	243,029	243,029	77,081	246,385	235,480	235,480	20,018	257,008	257,008	20,018	257,008

** INDICATES REQUEST OF FOLLOWING HEADERS: FISCAL YEAR AVERAGE PARTICIPATION, FOURTH QUARTER AVERAGE PARTICIPATION, OR SEPTEMBER PARTICIPATION. THE REQUEST HEADLINE IS THEN USED IN DETERMINING CASELOAD FOR THE NEXT FISCAL YEAR.

COMMODITY SUPPLEMENTAL FOOD PROGRAM
ELDERLY CARELOAD

STATES	FISCAL YEAR 1990				FISCAL YEAR 1991				FISCAL YEAR 1992				FISCAL YEAR 1993				FISCAL YEAR 1994			
	STATES' REQUEST FOR EXPANSION CARELOAD	TOTAL AUTHORIZED CARELOAD	** CARELOAD USED	STATES' REQUEST FOR EXPANSION CARELOAD	TOTAL AUTHORIZED CARELOAD	** CARELOAD USED	STATES' REQUEST FOR EXPANSION CARELOAD	TOTAL AUTHORIZED CARELOAD	** CARELOAD USED	STATES' REQUEST FOR EXPANSION CARELOAD	TOTAL AUTHORIZED CARELOAD	** CARELOAD USED	STATES' REQUEST FOR EXPANSION CARELOAD	TOTAL AUTHORIZED CARELOAD	** CARELOAD USED	STATES' REQUEST FOR EXPANSION CARELOAD	TOTAL AUTHORIZED CARELOAD	** CARELOAD USED		
New Hampshire	0	0	0	9,000	0	0	9,000	1,402	1,402	9,000	1,402	0	9,000	1,402	1,402	9,000	4,015	0		
New York	0	0	0	1,000	0	0	500	0	0	0	0	0	0	0	0	0	0	0		
D.C.	0	0	0	0	0	0	1,000	0	0	0	0	0	0	0	0	0	0	0		
Kentucky	2,500	3,216	3,186	2,000	3,306	3,386	2,000	3,915	3,915	2,000	3,915	0	2,200	3,915	0	1,000	5,115	0		
N. Carolina	0	1,702	1,527	1,000	1,527	1,527	0	1,722	1,722	0	1,722	0	2,500	1,519	0	90	1,650	0		
Tennessee	5,000	11,704	11,359	2,000	12,359	12,359	5,000	12,660	12,660	5,000	12,660	0	2,500	12,660	0	5,000	15,871	0		
Illinois	3,665	3,381	3,101	2,619	3,425	3,425	2,375	7,000	6,425	2,375	7,000	0	700	6,202	0	1,864	7,000	0		
Michigan	9,000	33,911	32,363	16,000	32,363	32,363	12,000	49,346	39,494	12,000	49,346	0	15,450	39,494	0	9,148	45,440	0		
Minnesota	0	0	0	7,000	0	0	17,000	2,347	2,347	17,000	2,347	0	17,000	2,347	2,347	133	2,500	0		
Red Lake	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Louisiana	15,001	26,478	26,478	15,001	25,478	25,478	25,000	31,422	31,422	25,000	31,422	0	25,000	31,422	31,422	15,000	36,553	0		
New Mexico	0	0	0	0	0	0	0	2,289	2,285	0	2,285	0	5,000	2,285	2,285	6,000	5,204	0		
California	2,000	5,354	5,100	0	5,100	5,100	1,294	6,422	6,037	1,000	6,937	0	1,000	6,937	6,937	1,507	7,809	0		
Idaho	0	4,743	4,571	0	4,571	4,571	291	4,660	4,216	0	4,216	0	0	4,216	3,976	424	4,400	0		
Utah	0	0	0	0	0	0	425	1,171	1,171	0	625	0	0	1,171	1,171	798	2,426	0		
Nebraska	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
South Dakota	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Arizona	1,000	3,071	3,071	18,200	4,071	3,951	17,929	7,534	6,781	0	6,781	0	7,714	6,781	6,781	5,215	9,240	0		
California	0	2,724	2,707	200	2,707	2,707	500	3,029	3,029	0	3,029	0	500	3,029	3,029	0	3,229	0		
Oregon	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
TOTALS	37,426	111,456	108,615	77,754	116,339	112,762	98,314	165,717	162,750	90,093	162,750	0	90,093	162,750	161,426	58,019	173,788	0		

** INDICATES REQUEST OF FOLLOWING MEMBERS: FISCAL YEAR AVERAGE PARTICIPATION, FOURTH QUARTER AVERAGE PARTICIPATION, OR SEPTEMBER PARTICIPATION. THE HIGHEST NUMBER IS THEN USED IN DETERMINING CARELOAD FOR THE NEXT FISCAL YEAR.
*** REPRESENTS INITIAL 4,548 EXPANSION SLOTS AND SUBSEQUENT APPROVAL OF 9,146 EXPANSION SLOTS AND 10,236 CONVERSION SLOTS FROM YOUNG, INFANTS AND CHILDREN.

Mr. DURBIN. It was stated during last year's hearing that as the WIC program moves toward full funding, you would expect decreases in participation by women, infants and children in CSFP. Looking at the estimates for participation in fiscal years 1994 and 1995 for women, infants and children, this does not seem to be the case. Has the Department changed its views on this issue?

Mr. LUDWIG. The Administration's estimates for fully funding the Special Supplemental Food Program for Women, Infants, and Children (WIC) including maintaining current levels of Commodity Supplemental Food Program (CSFP) participation by WIC eligibles. Otherwise, full funding would cost about \$100 million more. The effects of increased funding for WIC on participation levels in CSFP is difficult to predict. There are a variety of reasons why we believe the effects may be minimal. In certain areas of the country, WIC and CSFP do not serve overlapping service areas; in others, lack of access to retail food outlets may be a factor in sustained participation of women, infants, and children in CSFP. Further, some women and children served by CSFP would not be categorically or nutritionally eligible for WIC. We are researching this further to get better data on the mix of CSFP participants.

The Food and Nutrition Service (FNS) assures the maintenance of CSFP WIC eligibles participation as part of the 1995 Budget and out years. Consequently, we assume in Fiscal Year 1994 and subsequent fiscal years that participation of this target population will remain constant in CSFP and funding to support this participation contributes to our overall goal of fully funding WIC.

Mr. DURBIN. In fiscal year 1993, funds were available to support a caseload allocation of 236,148 women, infants and children and 152,489 elderly. The average monthly participation during the same fiscal year was 229,181 women, infants and children and 141,634 elderly. Why is there such a difference between caseload allocations and monthly participation levels?

Mr. LUDWIG. CSFP caseload is allocated on December 1 of each year, according to funds available. State agencies request expansion caseload based on their estimates of the unserved CSFP eligible population.

When new caseload is allocated, States need to conduct outreach to attract and gear up to serve new participants. In preparing to serve the increased as the year progresses. As such, year end participation is usually higher than average participation was 235,103 women, infants, and children and 152,000 elderly.

Mr. DURBIN. What was the total amount spent on the projects in Detroit, New Orleans, and Des Moines for fiscal years 1992, 1993, and 1994. How much do you anticipate spending in these areas in fiscal year 1995?

Mr. LUDWIG. I will submit the information for the record.
[The information follows:]

Project	Total—	
	WIC and elderly	Elderly
Fiscal year 1992:		
Detroit ¹	\$15,187,053	\$5,771,081
New Orleans	14,064,135	6,750,784
Des Moines	1,383,857	968,699

Project	Total—	
	WIC and elderly	Elderly
Fiscal year 1993: ²		
Detroit ¹	15,893,150	5,880,465
New Orleans	14,824,000	7,856,720
Des Moines	1,314,000	906,660
Fiscal year 1994: ²		
Detroit ¹	17,349,800	6,939,920
New Orleans	16,446,000	8,551,920
Des Moines	1,464,000	1,010,160

¹ Figures represent a percentage of total funding for Michigan based on the percentage of participants served in Detroit since Fiscal year 1992.

² Figures are estimates and are not official until final reports are submitted.

Note.—Fiscal Year 1995 spending in these areas will depend on the amount of funding the program receives and the caseload served in each area.

FOOD STAMP RESERVE

Mr. DURBIN. Included in the fiscal year 1994 appropriation is a reserve of \$2.5 billion, which is available until September 30, 1994. How much of this reserve has been used so far this fiscal year?

Mr. LUDWIG. To date, none of the reserve of \$2.5 billion has been used.

Mr. DURBIN. How much of the fiscal year 1993 reserve was returned to the Treasury?

Mr. LUDWIG. All of the 1993 \$2.5 billion reserve expired.

Mr. DURBIN. Your budget request for fiscal year 1995 includes a reserve of \$2.5 billion to be available until September 30, 1995. In addition to this request you are also proposing language to allow indefinite spending authority after May 31, 1994. Help me understand the need for this indefinite spending request. The project statement table in the explanatory notes show an unobligated balance of \$2.8 billion expiring at the end of fiscal year 1994 and \$2.5 billion expiring at the end of fiscal year 1995.

Mr. LUDWIG. The language requests indefinite spending authority after May 31, 1994 to ensure that program benefits are sufficient to cover the cost of any unforeseen economic conditions or other circumstances that might cause an increase in required program payments. The advance appropriation of funds would enable program operations to continue and ensure efficient and uninterrupted delivery of food stamp benefits. The Administration's budget would make Food Stamps consistent with other large low income entitlement programs such as Aid to Families with Dependent Children, AFDC, and Supplemental Security Income, SSI, which already receive indefinite authority and advance appropriations.

Mr. DURBIN. Since fiscal year 1991, Congress has provided the Food Stamp program with a reserve appropriation to be used for unanticipated costs. Would you tell the Committee how much of the reserve was actually used for each fiscal year.

Mr. LUDWIG. I will submit that information for the record.

[The information follows:]

[In billions of dollars]

	Fiscal year—		
	1991	1992	1993
Reserve appropriation	\$1.5	\$1.5	\$2.5
Amount used	1.4	0.9	0

ADVANCED APPROPRIATIONS

Mr. DURBIN. You are also proposing, as part of the budget request, language requesting \$7.2 billion in advance appropriations for the first quarter of fiscal year 1996. The first quarter ends on December 31, 1995, but you request that the funds remain available until September 30, 1996, which is the end of the fiscal year. Please explain the need for this advance appropriation and the reason it should be made available until the end of the fiscal year.

Mr. LUDWIG. The advance appropriation of funds for Fiscal year 1996 would enable program operations to continue and ensure efficient and uninterrupted delivery of food stamp benefits.

Mr. DURBIN. The budget request includes \$13,253,000 in discretionary additions to the mandatory baseline. For the record please provide a table showing the breakout of this discretionary spending in the food stamp program from the baseline year through the fiscal year 1995 budget request.

Mr. LUDWIG. I will submit that information for the record.

[The information follows:]

[Dollars in thousands]

	1991 base	(+/-)	1992 BA	(+/-)1	1993 BA	(+/-)	1994 BA	(+/-)	1995 BA
Computer Support	1,457	-187	1,270	+1,100	2,370	-874	1,496	+460	1,956
Printing other than stamps	500	+350	850	-350	500	+14	514	+13	527
Research	10,600	-731	9,869	-269	9,600	+1,286	10,886	+794	11,680
State exchange	359	-30	329	+30	359	+10	369	+10	379
Food Stamp litigation/claims	212	-12	200	+99	299	-81	218	+587	805
EBT	610	-110	500	+110	610	+9,997	10,607	—	10,607
Retailer integrity	1,950	+50	2,000	-50	1,950	+9	1,959	+28	1,987
Error reduction	—	—	—	—	—	—	—	+1,000	1,000
Nutrition education	—	—	—	+500	500	+14	514	-514	—
Total	15,688	-670	15,018	+1,170	16,188	+10,375	26,563	+2,378	28,941

FEDERAL TAX REFUND OFFSET

Mr. DURBIN. You anticipate a change in liabilities and collections from \$1.0 million in fiscal year 1994 to \$21.6 million in fiscal year 1995. This savings is primarily the result of anticipated increased collections through the Federal Tax Refund Offset program. When was this program started? What is the cost to operate the Program? How much has actually been collected since its inception?

Mr. LUDWIG. The collections from the Federal Tax Refund Offset, (FTROP) were not included in this section of the Agency's Budget report for Fiscal Years 1992-1994. They were included in preliminary planning for Fiscal Year 1995 when it was initially envisioned that (FNS) would collect \$21.6 million.

Food Stamp State agencies participating in FTROP collected \$3.5 million in Calendar Year 1992 and \$8.7 million in Calendar Year 1993. Collections are expected to be in excess of \$25 million for Calendar Year 1994. The amount of collection is always dependent on the amount and collectability of the delinquent debt forwarded for offset in any given year.

For the FNS, the receipt of collections attributed to FTROP began with Fiscal Year 1992. The project began as a demonstration effort with the Alabama and California Food Stamp State agencies. In 1993 the effort expanded to nine State agencies and is currently underway in 21 State agencies. The total collection, to date, is in excess of \$35 million. In May of this year, FNS will train an additional 13 State agencies to join the effort for the 1995 Calendar Year.

The operation of the FTROP Program is jointly the responsibility of FNS and its participating State agencies. The IRS charges a processing fee per offset of \$8.35 in 1994. This cost is shared between FNS and its State agencies.

FNS does not require its State agencies to isolate their operating costs for this effort from the standard reported costs for certification, fraud pursuit, issuance, etc. FNS reimburses State agencies at a standard matching rate of 50% for most State agency activity related to the operation of the Food Stamp Program.

The Program debt referred to the IRS is very specifically limited to delinquent recipient claims, unpaid recipient overissuances from former Food Stamp recipients. As in all collections for recipient overissuances, State agencies are allowed to retain a portion of the collections received through FTROP as a reimbursement for pursuing collection activities.

State agencies retain 10% of all collections for nonfraudulent, client caused overissuances and 25% for fraudulent overissuances. Overissuances produced as a result of State agency caused error are not referred to FTROP.

Mr. DURBIN. Provide a table for the record showing the number of States participating in the program, the amount collected from Federal tax refunds, and the amount in administrative costs to run the program for each of the fiscal years the program has operated.

Mr. LUDWIG. FNS does not require participating State agencies to break out the administrative costs for the Federal Tax Refund Offset Program from other costs associated with the operation of the Program. I will submit a table for the record which will include the number of State agencies participating, the FNS Federal costs to operate the Program and the collections, to date for the three years of operation.

[The information follows:]

Year	Number of States participating	FNS's reported costs for Federal operation	Collections due to FTROP (in millions)
1992	2	\$308,000	\$2.5
1993	9	698,000	8.7
1994	21	1 983,000	² 25.0

¹ Federal operating costs are estimated at this level.

² Twenty-five million was the original, conservative estimate for the current year collections. Approximately \$23 million has been collected between January 1, 1994, and March 31, 1994. Collections are now estimated for the year to be in excess of \$25 million.

BLOCK GRANT PROGRAMS

Mr. DURBIN. Puerto Rico and the Commonwealth of the Northern Mariana Islands operate block grant programs in lieu of the regular food stamp program. When was this program started in the Commonwealth of the Northern Mariana Islands? What is the funding level of this program in fiscal year 1994? What is the fiscal year 1995 budget request? Why isn't there a separate request for the Islands similar to the request for Puerto Rico?

Mr. LUDWIG. The Block Grant Program was started on June 30, 1992. The funding level for Fiscal Years 1994 and 1995 is \$3.7 million, respectively. The difference between the funding for the nutrition assistance programs for the Commonwealth of the Northern Marianas (CNMI) and Puerto Rico is explained by the different legislative origins for the two programs. Puerto Rico's Nutrition Assistance Program was authorized in 1981 by P.L. 97-35 which amended the Food Stamp Act to replace an existing food stamp program in Puerto Rico. The authorizing legislation also included a separate authorized funding level which has been amended periodically. On the other hand, the CNMI program was authorized by Section 502 of P.L. 94-241, the "Covenant to Establish the Northern Mariana Islands in Political Union with the United States of America" (90 Statute 263). So, while CNMI is not mentioned as an eligible jurisdiction in the Food Stamp Act, it is covered by this law. The Food Stamp Act has never been amended to authorize the CNMI nutrition assistance program and there has never been separate funding authorization.

ELECTRONIC BENEFIT TRANSFER

Mr. DURBIN. Maryland went statewide with an Electronic Benefit Transfer system, EBT, in April of 1993. Since this was the first, large-scale program of its kind, the Committee directed the Secretary to perform a detailed analysis of the program and submit the findings and recommendations to the Appropriations Committees by March 1, 1994, prior to the fiscal year 1995 budget hearings. It is now March 23, 1994. When can we expect to receive this report?

Mr. LUDWIG. The evaluation of the Electronic Benefit Transfer system, EBT, was launched in October 1991. Although EBT was operating in every county by April 1993, complete statewide implementation was not achieved until July 1993. This represented a six-month delay beyond the original project schedule and required that data collection activities be postponed. Final data collection was completed in September 1993.

All data have now been coded and analyzed. The Food and Nutrition Service and Administration for Children and Families are currently in the process of reviewing the final report of the evaluation. We expect to release the report in June.

Mr. DURBIN. Since Maryland borders five other States that still use a coupon system, authorized stores must accept both coupons and EBT cards. How costly is this to the program?

Mr. LUDWIG. Authorized food retailers are not compensated by the program for accepting and redeeming food stamps or Electronic Benefit Transfer (EBT) transactions. Thus, costs they might incur

by having to operate dual systems are not charged to any program account. Likewise, financial institutions in border areas that accept both electronic and food stamp deposits from food retailers are not compensated by the Food Stamp Program.

Mr. DURBIN. There are EBT projects operating in Ohio and Iowa. Would you please tell the Committee where these projects are located and the status of each.

Mr. LUDWIG. An off-line Electronic Benefit Transfer (EBT) food stamp demonstration project utilizing smart cards has been operating in Dayton, Ohio since June 1992. Unlike on-line systems which store benefit accounts in a host computer, off-line systems store accounts on a micro-chip EBT card. The off-line transactions are authorized from the micro-chip card rather than telephonically from the host computer. Ohio now plans to implement a statewide EBT system utilizing the same technology and, towards that end, issued a Request for Proposals in February 1994.

The State of Iowa began operating a voluntary EBT system in Linn County (Cedar Rapids) for food stamp benefits in April 1993. The system provides AFDC benefits as well. As of early 1994, 19 food retailers were participating and 710 of 4,400 food stamp households in the county chose to receive their benefits via EBT. Over 1,000 AFDC households were receiving benefit via EBT.

Mr. DURBIN. Provide the Committee with a complete list and the status of all EBT plans of each State.

Mr. LUDWIG. I will provide a list and the status of all Electronic Benefit Training (EBT) system plans of each State for the record.

[The information follows:]

**FOOD STAMP PROGRAM
ELECTRONIC BENEFITS TRANSFER (EBT)
PROJECT STATUS**

February 1994

Alabama

- Alabama Planning Advance Planning Document (APD) for food stamp and AFDC system contingently approved September by FNS and shortly afterwards by ACF.

California

- California submitted a revised EBT Planning Advance Planning Document (PAPD) in September 1993; PAPD is for food stamps only, with the option to add AFDC at a later date.
- Pilot includes San Bernardino County and San Diego County, comprising approximately 100,000 food stamp households.
- PAPD was contingently approved in December 1993.
- State plans to submit IAPD and RFP in February and March 1994 respectively.

Delaware

- Delaware submitted concept paper for off-line EBT demonstration project using optical laser card for food stamps and WIC (Special Supplemental Food Program for Women, Infants and Children) in August 1993.

Florida

- Florida submitted EBT project Planning APD for food stamps and AFDC.
- The State's Planning APD was approved by the Food and Nutrition Service (FNS) Oversight Committee December 31, 1993. ACF has also approved the planning costs. Planning will entail food stamps, AFDC and WIC.

Georgia

- Georgia submitted EBT project Planning APD for a food stamps & AFDC in November 1992.
- Fulton and DeKalb Counties (Atlanta area) proposed pilot sites.
- In early 1993, Planning APD contingently approved with clarifications.

Kansas

- Kansas' EBT project Planning APD contingently approved in December 1992 for multi-benefit EBT system to deliver food stamps, AFDC and medicaid benefits.
- Final approval of Planning APD given in August 1993 after receipt of budget and cost allocation revisions.
- State plans to conduct their own needs assessment, feasibility study, and cost-benefit analysis.
- State is working on Implementation APD.

Illinois

- Illinois' Planning APD contingently approved in 1992 for a multi-benefit EBT system.
- The State proposed two pilot sites: one in a rural Sangamon County; the other in several urban zip codes of Chicago
- These two sites include nearly 1200 authorized retailers and 29,000 FSP households.
- Final Implementation APD submitted December 1993.
- Final Implementation RFP expected January 1994.

Iowa

- Iowa began operating a voluntary EBT system in Linn County (Cedar Rapids) issuing AFDC benefits through the Iowa Transfer System (ITS) network in April 1993.
- As of June 1, 1993, the State offers over 4,400 food stamp households in Linn County a choice of receiving food stamp benefits via EBT or food coupons.
- By first of 1994, 710 food stamp households and 19 food retailers were participating in EBT. Over 1,000 AFDC households were receiving benefits via EBT.

Maryland

- In November 1989, began operating in one district of Baltimore City a multi-benefit demonstration EBT system which included food stamps and AFDC benefits, State funded general assistance benefits and child support payments.
- The State completed statewide expansion in April 1993.
- Over 3,000 authorized retailers are now on the system.
- With statewide expansion in June 1993, over 150,000 assistance households using EBT to receive food stamps, AFDC, general relief and child support payments.
- Final project evaluation report is scheduled for completion in June 1994.

Michigan

- Michigan submitted Planning APD to develop a multi-benefit EBT system including food stamps, AFDC, medicaid, State disability assistance, State family assistance, refugee assistance, WIC, and day care payments in June 1992.
- In August 1992, FNS approved State's EBT Planning APD to begin the planning activities.
- Proposed pilot site is Jackson County, near Lansing.
- The region sent a letter to the State January 26, 1994, asking the State to submit an update on the status of the project to determine if the PAPD should be closed out.

Mississippi

- Mississippi Planning APD for food stamp only system contingently approved June 1993.
- State legislation mandated on-line EBT system in five counties.

Missouri

- Missouri revised Planning APD approved in December 1992.
- State proposes a multi-benefit system to provide food stamps, AFDC, Medicaid, and WIC benefits electronically in Jackson and St. Louis Counties.
- EBT system to piggyback on existing commercial POS devices
- Submitted draft Request for Proposal (RFP) for planning in May 1993. FNS returned comments to State September 1993. Revised draft submitted December 1993. FNS HQ returned comments with contingent approval February 1994.

New Hampshire

- FNS approved a Planning APD submitted by New Hampshire for a tri-state EBT system with New Hampshire, Vermont and Maine in 1992.
- The proposed tri-state system would provide food stamps, AFDC and Medicaid benefits, and child support payments across state borders.
- Policy Studies, Inc., hired to conduct a feasibility study and cost benefit analysis for the multi-State EBT system
- Final draft of Feasibility Study released in May 1993.
- States reviewing feasibility study to determine next step for EBT project.

New Jersey

- New Jersey is approved EBT demonstration project site.
- State proposed a project pilot site in Camden, Essex, and Hudson Counties encompassing nearly 80,000 FS cases and 60,000 AFDC cases.
- State awarded EBT contract to Deluxe Data Systems.
- evaluation contract has been awarded to Market Facts.
- Pilot operations to begin in Camden County in February 1994.

New Mexico

- EBT operations began in Bernalillo County (Albuquerque) in September 1990 with countywide expansion completed by April 1992.
- Currently, over 23,000 food stamp households and 8,000 AFDC households participate in the New Mexico EBT project.
- Over 160 food stamp authorized retailers now accept New Mexico's EBT card.
- New Mexico began expansion in Phase I (of six) in the four counties adjacent to Bernalillo County in December 1993.

North Dakota/South Dakota

- The States submitted Planning APD for two-State EBT project for issuing food stamp benefits only with the option of adding AFDC cash later.
 - Bismarck, North Dakota, and Rapid City, South Dakota, chosen as pilot sites.
 - Planning APD approved in June 1993.
 - Planning activities expected to be completed by October 1993
 - The States submitted Implementation APD in June 1993.
- Approval is pending submittal of the Implementation RFP.

Ohio

- Dayton, OH is the site for the only food stamp offline EBT demonstration project.
- Project covers a six zip code area in Dayton, includes about 11,000 food stamp households, 94 retailers, and has fully implemented since June 1992.
- The system is operated by the National City Processing Company (NPC) of Louisville, KY under contract with FNS.
- The offline system benefit accounts are on a micro-chip in the card, unlike online systems where benefits are on the host computer.
- Telecommunications to a host computer are not needed for each purchase, but only for daily settlement.
- Based on preliminary evaluation results, the State asked for and FNS approved plans for a statewide offline system.
- On 3/1/94, OH released an RFP to hire a vendor for their offline system.

Oklahoma

- Oklahoma submitted an EBT APD to develop and operate a food stamp only EBT project.
- The state plans to add AFDC and child support payments later.
- State's Request for Proposal (RFP) for EBT vendor reviewed by FNS; comments sent to the State agency in January 1993.
- Revised Request for Proposals (RFP) received from Oklahoma in June 1993.
- Comments on the second draft RFP were sent to the State agency in December 1993.

Oregon

- Oregon formed a task force to bring EBT to the State.
- Congressmen Wyden and Kopetski, as well as FNS' WRO, active in this effort and participating on task force.
- Oregon's EBT project Planning APD approved in April 1993 for food stamps and AFDC.
- State released Request for Proposals (RFP) and in December 1993 hired a planning contractor.

Pennsylvania

- Reading, Pennsylvania (Berks County) first EBT demonstration project in the nation, implemented in October 1984.
- After 9 years of operation, Reading's system is no longer a demonstration and serves over 8,700 food stamp households through 126 authorized food retailers.
- Pennsylvania's Department of Public Welfare (PDPW) is the EBT processor and switch.
- In June 1993, Pennsylvania submitted Planning APD for development of statewide EBT system to deliver food stamps, AFDC, general assistance and other programs.
- Planning APD was approved in September 1993.
- Pennsylvania plans to pilot the multi-program system in Berks County and Philadelphia.

Ramsey County, MN

- Ramsey County (St. Paul), Minnesota, began a voluntary cash assistance EBT system in 1987, providing AFDC, general assistance, refugee assistance and State supplemental security income via an on-line transfer system.
- The mandatory issuance of food stamp benefits by the EBT system began in September 1991 with the full caseload implemented by May 1992.
- Over 19,500 food stamp households and 14,000 cash benefit households were participating in EBT by the end of 1993.
- 313 authorized food retailers also participate.
- Minnesota began submission of an expansion APD in August 1993 to expand Ramsey County's system into neighboring Hennepin County (Minneapolis). Pieces of the APD continue to come in for review as they are completed by the State.
- Such an expansion, which would encompass nearly 50 percent of the Minnesota's food stamp caseload.
- The State legislature has mandated that an RFP for a new EBT contract be released by 1/95.

South Carolina

- South Carolina proposes to implement a food stamp-only EBT system.
- The State released a Request for Proposals (RFP) in October 1992 to hire a vender to develop and operate the State's EBT system.
- State agency staff are now reviewing four bids.
- Darlington County, which is more than 50 percent rural, is the proposed pilot site.
- If the pilot is successful and cost effective, State plans statewide expansion to begin in the Charleston area.

Tennessee

- Tennessee is looking at EBT options for food stamps, WIC, AFDC, Medicaid, and Child Support.
- Although some support for funding in the State legislature, State has not submitted EBT proposals or planning documents.

Texas

- Texas' EBT project Planning APD was approved in April 1992.
- The State proposed a food stamps and AFDC EBT system initially with other State and Federal programs possibly added in the future.
- Harris (Houston) and Chambers Counties area selected as the EBT project pilot site, representing over 200,000 public assistance cases.
- State released a Request for Proposal (RFP) in March 1993 to hire a vendor to develop and operate the State's EBT system.
- Two vendors submitted proposals in response to the State's RFP, both of which were rejected because they were too high.
- Using a Catalogue Version of the RFP process, the State began negotiations with five vendors. On February 10, 1994 the TDHS announced that they had awarded the contract to GTASCO, a subsidiary of GTECH of West Greenwich, Rhode Island. GTECH operates the New York City Benefit Delivery system and lottery systems throughout the world.
- The pilot is scheduled to begin in September, 1994, with statewide rollout scheduled to begin in early 1995.

Utah

- Utah submitted EBT project Planning APD for multi-benefit project to include food stamps, AFDC, Medicaid, and WIC in March 1993.
- The Planning APD was approved in August 1993.
- Utah recieved the feasibility study from planning contractor, BDM, in 12/93 which advised the State to move forward with FSP and AFDC only.

Wyoming

- Wyoming conducted the only EBT off-line test for WIC program in Casper involving over 700 participants and 4 retailers. Project suspended in August 1992.
- National City Processing Company of Louisville, KY will design and operate the combined food stamp/WIC off-line demonstration. Design work commenced in December 7, 1993.
- Abt Associates is evaluating the demonstration for USDA/FNS.

Mr. DURBIN. Mr. Ludwig, you made a statement in your testimony that EBT provides new opportunities for fraud. Would you elaborate on this for the Committee. Maybe you could provide some examples as well.

Mr. LUDWIG. While the Electronic Benefit Transfer system (EBT) is an important tool for fighting fraud, we recognize that it may bring new opportunities for fraud as well. First, as with any computer system, there may be opportunities for breaches of system security. FNS takes this possibility very seriously, however, and we rigorously test all EBT systems before they are implemented. In addition, we are currently conducting a study on EBT security which is looking closely at the risks posed by EBT systems and will recommend safeguards that should be implemented.

Another new opportunity for fraud is presented by the extension of Regulation E to EBT. The "Regulation E" liability provisions which would limit recipient liabilities for lost or stolen benefits will make the program vulnerable to forms of recipient fraud that currently do not exist. One of the principal purposes of our planned demonstrations of Regulation E coverage is to measure the cost of extending such coverage, some of which could be attributed to fraudulent claims.

"Regulation E", beginning in 1997, limits consumer liability to \$50 when their credit or debit cards are lost or stolen. It would also limit food stamp recipient liability to \$50. A lost or stolen card with protected Personal Identification Number (PIN) presents no problem for EBT because anyone using the card must have the PIN. However, if the recipient sold his/her card and PIN, just like some now sell their food stamps, a purchaser with food stamp redemption rights could redeem all of the EBT benefits. However, since "Regulation E" would limit recipient liability to \$50, the recipient who sold the benefits could claim that the card was lost or stolen and be reimbursed. Procedures will be developed to limit program exposure to recipients who repeatedly "lose" their cards in such a manner that all the benefits are drawn down on them. And, of course, enforcement mechanism will continue to be part of the program.

WELFARE REFORM

Mr. DURBIN. Describe the welfare reform project that will operate in Utah through February, 1998.

Mr. LUDWIG. The Single Parent Employment Demonstration Program, SPED, began in January 1993. It is designed to change the Aid to Families with Dependent Children (AFDC) Program from an income maintenance program to an employment program with the goal of increased family income through employment and child support. The demonstration project is being operated in three counties for a five-year period.

SPED modifies the terms and conditions of certification for households participating in the project by disregarding certain types of income and resources; allowing the State to extend the 12-month face-to-face recertification requirement for up to two years for reporting income changes in certain cases; increasing the threshold from \$25 to \$50 per month for reporting income changes in certain cases; allowing case managers to determine which eligi-

bility factors to verify and which to accept based on the applicant's or recipient's declaration; based on criteria established for SPED case management; and allowing participants the option of receiving food stamp benefits in the form of coupons or a check.

One objective of the demonstration is to increase the incomes of most participants to above the poverty level through participation in self-sufficiency activities and the provision of supportive services. The program also provides a one-time payment to divert appropriate applicants from requiring long-term assistance. These diversion payments can be any amount up to three times the monthly cash grant for a family of its size.

Along with the diversion payment, families earning income are entitled to three months of Medicaid and child care benefits. If, after three months, the family does not end up on AFDC and still has an income need, it is eligible for 12 months of transitional benefits.

Families who reapply for AFDC within three months of receiving the diversion payment will have their assistance payments reduced by the amount of the diversion payment prorated over a three month period. There is nothing that would prohibit a family from applying for AFDC beyond the three month period.

The demonstration program is expected to cost Utah an additional \$1.2 million, but is expected to save more than that amount over the five year period of the demonstration.

FOOD STAMP CASH-OUT PROJECTS

Mr. DURBIN. I read in the explanatory notes where one county in the States of California, Ohio, and Virginia, four counties in Oregon, and two counties in Wisconsin will begin operating cash-out projects in 1994. Would you describe each of these projects in further detail and tell the Committee how they relate to the Secretary's announced goal of initiating EBT systems in all States by 1996.

Mr. LUDWIG. The Ohio, Virginia, and Oregon cash-out projects are designed specifically for the elderly and disabled. Authorized by section 17 of the Food Stamp Act, as amended, these projects provide cash benefits in lieu of coupons for persons over 65 and recipients of Supplemental Security Income (SSI) benefits. SSI/Elderly Cash-out demonstrations are also operating in the States of New York, Utah, Vermont, and Minnesota. The projects have operated for over 10 years and have repeatedly been extended by Congress in reauthorization of the Food Stamp Program.

San Diego, California has been operating a "pure" cash-out demonstration since 1989. There are no treatments other than cash-out. The demonstration was designed to test the effects of cash-out. Results of the study show a reduction in food expenditures when coupons are converted to cash.

The State of Wisconsin was recently approved to cash-out food stamp benefits as part of its welfare reform demonstration entitled, "Work Not Welfare." Food stamp benefits will be cashed out for public assistance cases only and consolidated with the Aid to Families with Dependent Children Program grant in a monthly check. The project will affect approximately 4,000 households.

Many other States are proposing cash-out as part of their welfare reform efforts. Proposals from Maryland, Pennsylvania, Mississippi, Missouri, Michigan, and Oregon are under review at this time.

The Department remains committed to its goal of implementing Electronic Benefit Transfer (EBT) technology for the delivery of food stamp benefits in all States by 1996. EBT is preferred to cash-out because it maintains the direct link between food stamp benefits and food purchases while reducing the cost and stigma associated with paper coupons.

We believe there is room to accommodate both types of approaches. Cash-out is approvable on a limited basis as long as there is a strong commitment by the State to implement EBT. In addition, a nutrition education component will be required for demonstration participants to help ensure that nutritional status will not be eroded by the conversion of benefits to cash.

Mr. DURBIN. An evaluation of a cash-out project conducted in Minnesota showed that misuse of the benefit check was properly controlled. Would you explain how this worked in greater detail.

Mr. LUDWIG. In response to a State law which required same-day issuance of benefits for expedited service recipients, Minnesota was given approval to conduct a demonstration project whereby the State issues one quarter of the first month's benefits in cash to households in need of expedited benefits. The remainder of the first month benefits are issued in coupons by mail.

In effect, the State has pointed out in its report that it has controlled the misuse of the benefit check by limiting the amount to one quarter of the initial month's benefits.

ADMINISTRATIVE EXPENSES

Mr. DURBIN. Beginning April 1, 1994 all State welfare administrative expenses will be limited to a 50 percent match with Federal funds. I know its a few weeks before April 1, but can you give the Committee a preliminary assessment of what the impact of this decision will be?

Mr. LUDWIG. Beginning April 1, 1994, State welfare administrative expenses for fraud control, automated data processing system development, and the Systematic Alien Verification for Entitlement System will be limited to a 50 percent match with Federal funds for most State agencies. The Office of Management and Budget estimates that this will result in Federal savings of \$20 million in Fiscal Year 1994 and \$40 million per year in Fiscal Years 1995 through 1998.

The Department has approved requests for a delay of the April 1, 1994 effective date for State agencies because each has a biennial State legislature which will not meet in regular session in Calendar Year 1994 and there was no realistic mechanism under the State law by which the State could appropriate the additional State funds prior to the next regular legislative session. The four approved State agencies are Arkansas, Montana, North Dakota, and Texas. We use the term "realistic mechanism" because two of these State agencies had funding mechanisms such as voter initiatives, which require time to be placed on the ballot and which are beyond the control of the State, and emergency funding provisions which

would have required State officials to declare an emergency to obtain the additional State funds.

The Department anticipates that there may be some level of cutback in State fraud control and automation activity because some State agencies had previously indicated that they may be unable to get the additional State funds from their State legislatures. Most annual State legislatures started their legislative session in January and in a number of States those sessions have just ended or are just ending. While some State agencies have informed us that there may be cutbacks in their fraud control and automation activity, we have no information at this time that there will be cutbacks.

The reduction in the Federal reimbursement rate for fraud control does not signal a lack of commitment by the Department to control fraud; rather the Department is shifting its emphasis from up-front funding through the Federal reimbursement rate for fraud control activity to performance-based funding through the State retention of claim collections. State agencies will still retain 25 and 10 percent of claims collected for intentional program violations and inadvertent household errors respectively. Furthermore, these retention rates are scheduled to increase to 50 and 25 percent in October 1995. Also, the Federal Tax Refund Offset Program provides an additional incentive for anti-fraud activity by making available a new cost-effective means of claim collections.

EMPLOYMENT AND TRAINING

Mr. DURBIN. States are required to conduct an employment and training program for participants in the Food Stamp Program. Briefly describe how the program is operated.

Mr. LUDWIG. Beginning April 1987, all States were required to operate a Food Stamp Employment and Training (E&T) Program. The program is designed to improve food stamp recipients' ability to gain employment, increase earnings and reduce their dependency on public assistance.

Food stamp recipients who are not exempt by Federal statute or State-specific exemptions are subject to the E&T Program. These individuals may face a two month disqualification from the Food Stamp Program for failure to comply with program requirements. If the noncomplying individual is the head of the household, the entire household is sanctioned. Exempt individuals may volunteer to participate in the program and are not subject to a sanction.

The E&T Program is State-designed; each State determines which services will best meet the needs of its recipients. State agencies may choose from a variety of employment and training activities, including job search and job search training, self-employment activities, on-the-job training, vocational training and basic education. Job search has been the most prevalent activity, as its relatively low cost and high number of placements has helped States achieve their performance standard.

Historically, the Department has advocated broad-based, low-cost employment and training programs. The performance standard reflected this philosophy. In Fiscal Years 1990 and 1991, States were required to serve at least 50 percent of their mandatory population. This standard was lowered legislatively to 10 percent for Fiscal

Year 1992 and beyond. This change enables States to serve fewer people and provide more intensive services.

The Federal Government provides \$75 million as a grant to the States to provide E&T services to recipients. Each States' share of the \$75 million grant amount is determined partially on performance. Expenditures above the grant amount are shared equally by the United States Department of Agriculture (USDA) and the States. USDA also matches half the cost to reimburse participants for transportation up to \$25 per month, and for dependent care up to \$160 per dependent per month.

Recent legislation will allow E&T dependent care reimbursements to conform with those under the Aid to Families and Dependent Children Job Opportunities and Basic Skills Training Program (which States will reimburse the actual amount of dependent care expenses up to at least \$200 a month for such dependent under age two and \$175 a month for each older dependent).

Mr. DURBIN. What was the total funding level for this program in fiscal year 1993? How many food stamp recipients participated in the program during the same fiscal year? How many of these recipients found employment as a result of this training?

Mr. LUDWIG. The total Federal obligations for the Food Stamp Employment and Training (E&T) Program for Fiscal Year 1993 were \$157.7 million. Obligations in each category will be submitted for the record.

[The information follows:]

Fiscal year 1993

	<i>Millions</i>
100 percent grant	\$74.7
50 percent expenditures	61.8
Dependent care expenditures	4.7
Participant reimbursement expenditures	16.5
Total	157.7

A total of 1.4 million placements into E&T components were made during Fiscal Year 1993.

The Food Stamp E&T Program does not collect data on the number of recipients who find employment as a result of participation in the program.

Fiscal Year 1993 expenditures are lower than those contained in the Administration's Budget submission because we now have actual close out data.

Mr. DURBIN. What is the funding level for this program in fiscal years 1994 and 1995? Provide a breakout of how these funds are used?

Mr. LUDWIG. The estimated Fiscal Year 1994 Federal funding level for the Food Stamp Employment and Training (E&T) Program is \$162.7 million. The estimated Fiscal Year 1995 Federal funding level is \$165 million. The breakout of these funds will be submitted for the record.

[The information follows:]

Fiscal year 1994

	<i>Millions</i>
100 percent grant	\$75
50 percent funding	63
Dependent care funding	5.5
Participant reimbursement funding	19.2
Total	162.7

Fiscal year 1995

	<i>Millions</i>
100 percent grant	\$75
50 percent funding	64
Dependent care funding	5.8
Participant reimbursement funding	20.2
Total	165.0

The numbers provided for Fiscal Year 1995 are estimates. Final information will not be submitted until August 1994.

Mr. DURBIN. Many of these participants also receive training and education through the JOBS program. Can you tell us how many food stamp recipients are also involved in the JOBS program?

Mr. LUDWIG. The Food Stamp Act of 1977, as amended, exempts recipients from food stamp work requirements if they are participating in the Job Opportunities and Basic Skills Training (JOBS) Program. Data is not available on the number of recipients who receive JOBS services.

In some instances, Food Stamp Employment and Training participants receive the same services provided to JOBS participants. State Food Stamp Program administrators arrange for these services through contract or cooperative agreement with the JOBS service provider. States are not required to report the number of food stamp recipients receiving services through JOBS.

Mr. DURBIN. In your opinion, is the Food Stamp Employment and Training Program operating efficiently and effectively? Is there a better way to achieve the same objectives?

Mr. LUDWIG. The Food Stamp Employment and Training (E&T) Program is probably not operating as effectively as it could. It has been hampered by relatively low funding levels to serve large numbers of eligible participants.

The E&T Program has been operating nationwide since April 1987. Its 100 percent Federal grant to States has remained constant at \$75 million since Fiscal Year 1989, while the food stamp work registrant population has risen by more than 50 percent.

From the start, the program's emphasis has been on broad-based, low-cost services. A USDA evaluation done in Fiscal Year 1988, the first full year of program operations, indicated that this was not an effective direction. The program was found to have no impact on earnings or employment. Since that time the Department changed the performance standards for the program from 50 to 10 percent which means the States must serve at least 10 percent of the eligible population rather than 50 percent. This enables States to serve fewer people and offer more intensive services. However, frustration with the program remains.

The huge disparity in Federal funding between the E&T Program and other employment programs, such as the Department of Health and Human Services' Jobs Opportunities and Basic Skills Training Program (JOBS) and the Department of Labor's (DOL) Job Training Partnership Act Program hampers smooth interactions between programs.

Mr. DURBIN. In fiscal year 1993, State agencies issued 442,657 Notices of Adverse Action to recipients who did not comply with work registration requirements. What action is taken against these recipients?

Mr. LUDWIG. Food Stamp Program regulations stipulate that if a State agency determines that an individual refuses or fails without good cause to comply with work requirements, the individual becomes ineligible to participate in the Food Stamp Program for a period of two months. If the head of the food stamp household fails to comply with work requirements, the entire household becomes ineligible for two months. Disqualified recipients may regain eligibility sooner by complying with work requirement that led to their disqualification.

Many persons who receive notices are not sanctioned because they come into compliance with program requirements or have evidence of good cause as to why they were not in compliance.

MICKEY LELAND CHILDHOOD HUNGER RELIEF ACT

Mr. DURBIN. The request includes increases of \$640,267,000 for benefit costs and \$14,865,000 for State administrative costs. Both of these increases include the effects of the Mickey Leland Childhood Hunger Relief Act. Provide a brief description of all provisions in the Act that effect the program as well as the amount included in the budget request to implement the provision.

Mr. LUDWIG. Public Law 103-66, the Omnibus Budget Reconciliation Act of 1993, Chapter 3 of which is the Mickey Leland Childhood Hunger Relief Act, approved August 10, 1993. I will provide a list of provisions in the Act that affected the Food Stamp Program for the record.

[The information follows:]

- Excluded as income of the household, earnings of elementary or high school students who are members of the household and are 21 years old or younger. (\$45 million)
- Eliminated incrementally, the shelter deduction cap. The cap will be \$231 from July 1, 1994, through September 30, 1995 (\$402 for Alaska, \$330 for Hawaii, \$280 for Guam, and \$171 for the Virgin Islands); \$247 from October 1, 1995, through December 31, 1996 (\$429 for Alaska, \$353 for Hawaii, \$300 for Guam, and \$182 for the Virgin Islands); and no cap beginning January 1, 1997. (\$1,465 million)
- Excluded earned income tax credits (EITCs) as resources for 12 months from receipt if the individual receiving the EITC was participating in the FSP when the EITC was received and participates continuously during the 12-month period. (< \$1 million)
- Excluded entire amount of vendor payments for transitional housing for the homeless. (\$20 million)
- Revised the provision on counting general assistance (GA) vendor payments as income so that only those vendor payments provided to cover housing expenses, exclusive of energy or utility expenses, are included as income. (\$20 million)
- Eliminated proration of benefits for households unless they are off the FSP for more than 1 month. (\$107 million)
- Increased Puerto Rico's Nutrition Assistance Program funding by \$6 million for Fiscal Year 1994 and \$10 million for Fiscal Year 1995. (\$46 million)
- Gave State agencies the option to provide a deduction for legally-binding child support payments made to nonhousehold members. By October 1, 1995, the deduction will become mandatory. Authorized the Secretary to establish, in regulation, the methods (which may include retrospective budgeting) to be used to determine the amount of the deduction. (\$455 million)
- Raised the cap on the dependent care deduction from \$160 to \$200 for children under 2 years old and \$175 for all other dependents. (\$4 million)
- Removed the specific dollar cap on dependent care reimbursements under the Employment and Training Program. States must pay the lower of actual expenses, the applicable local market rate (using procedures consistent with the Aid to Families with Dependent Children's Job Opportunities and Basic Skills Training Program), or a statewide limit that must be at least \$200 for children under 2 and \$175 for all other dependents. Provided 50 percent Federal funding for amounts State agencies reimburse up to the applicable market rate. (< \$1 million)

- Set the fair market value of vehicles which are excluded in determining households' resources at \$4550 for September 1, 1994 - September 30, 1995 and \$4600 for October 1, 1995 - September 30, 1996. From October 1, 1996, annually adjust the value using \$5000 as a base and the CPI-U for new cars for the 12 months ending the preceding June and rounding to the nearest \$50. (\$142 million)
- Excluded as resources the value of vehicles used to carry the primary source of fuel for heating or water for home use. (< \$1 million)
- Mandated that the Department conduct demonstration projects testing allowing food stamp households to accumulate up to \$10,000 in resources without losing their food stamp eligibility. Limited the demonstration projects to 4 years duration (beginning after September 30, 1993) and 11,000 households. Required households to maintain the additional resources in separate accounts and required that the resources be intended for one of the following purposes: (1) improving the education, training, or employability (including self employment) of household members, (2) purchasing a home for the household, (3) changing the household's residence, and (4) making major repairs to the household's home. (\$17 million)
- Simplified the household definition: children 21 years old and under living with their parents cannot be separate households from their parents unless they are married and living with their spouses and/or living with their children; children (other than foster children) who are under 18 years old and live under the parental control of an adult household member cannot be separate households; adult siblings who live together and adult children who live with their parents can be separate households if they purchase and prepare food separately; retained the Fenwick provision for separate household status of elderly, disabled people. (\$320 million)
- Permitted the children of drug addicts and alcoholics who live with their parents in treatment centers to qualify for food stamps. Made the meals served to those children by the centers eligible for purchase with food stamps. (\$4 million)
- Effective October 1, 1993, expanded the disclosure provision to permit collection of claims resulting from intentional program violations and inadvertent household errors by offsetting Federal pay. Authorized such claims collection. (-\$19 million)
- Disqualified recipients for 1 year for a first finding by a court that the recipient has purchased illegal drugs with food stamps and permanently for a second such finding or the first finding by a court that the recipient has purchased firearms, ammunition, or explosives with food stamps. (< -\$1 million)
- Effective October 1, 1993, raised the cap on civil money penalties for trafficking to \$40,000 per investigation. (< -\$1 million)
- Effective October 1, 1993, raised the cap on civil money penalties for selling firearms, ammunition, or explosives for food stamps to \$40,000 per investigation. (< -\$1 million)
- Modified the quality control (QC) system to:
 - Retroactive to October 1, 1991, permit interest to accrue if bills are not paid after 1 year
 - Retroactive to October 1, 1991, use each year's national performance measure to establish a State agency's liability

- Retroactive to October 1, 1991, calculate a State agency's liability by multiplying its issuance times the ratio of the amount the State agency's payment error rate exceeds the national performance measure to the national performance measure (but not greater than 1) times the amount the State agency's payment error rate exceeds the national performance measure
- Retroactive to October 1, 1992, exclude errors made in applying a new regulation for a 120-day period following the required implementation date (rather than 60 or 90 days)
- Retroactive to October 1, 1991, require that all case reviews and arbitrations be completed by March 29 (or March 28 in leap years) and require the Department to determine final error rates, the national average payment error rate, and billing amounts by April 28 (or April 27 in leap years)
- Retroactive to October 1, 1991, require that good cause determinations be made by administrative law judges (ALJs) rather than the Secretary
- Retroactive to October 1, 1991, provide the following timeframes relative to the ALJs' determination of billing amounts:
 - 10 days after the billing for the State agency to request an appeal
 - 60 days for the State agency to submit evidence in support of its appeal
 - 60 days for the Department to respond
 - 30 for State agency rebuttal, if any
 - 60 days after the submission of the State agency's rebuttal for the ALJs' decision or, if there is no rebuttal, 90 days after the State agency's original submission of evidence (60 of which are available to the Department for the preparation of its response)
- Authorize the ALJs to extend any of the above deadlines
- Retroactive to October 1, 1991, require the ALJs to hold evidentiary hearing upon the request of either the State agency or the Department
- Define "good cause" to include:
 - a natural disaster or civil disorder that adversely affects FSP operations
 - a strike by State agency employees who make eligibility determinations or process changes
 - significant growth (e.g., 15%) in a State's caseload
 - a FSP change or other Federal or State program change that substantially adversely impacts FSP management
 - a significant circumstance beyond the control of the State agency. (\$75 million)
- Effective April 1, 1994, provided 50 percent Federal funding for State agencies' administrative costs for automation, fraud investigations and prosecutions, and the Systematic Alien Verification for Entitlement system. Provided for later implementation for States whose legislatures do not have a regular session in Calendar Year 1994 and that have no mechanism under constitutions or State laws for appropriating the necessary additional funds before the next regular legislative session. (-\$180 million)
- Most provisions were effective September 1, 1994, unless otherwise indicated.

The amounts provided in parentheses are five-year (Fiscal Years 1994-98) costs. We estimate that the net effect of the Act will be an increase of \$256 million in Fiscal Year 1995. This amount was factored into the Administration's budget request.

FOOD STAMP BENEFIT LEVELS

Mr. DURBIN. The value of the Thrifty Food Plan is estimated to increase from \$364.90 in fiscal year 1994 to \$374.90 in fiscal year 1995. The maximum allotment in fiscal year 1994 is \$375 and is expected to increase to \$386 in fiscal year 1995. What is the difference between the Thrifty Food Plan and the maximum allotment?

Mr. LUDWIG. The Thrifty Food Plan is a low cost, nutritious model diet for a family of four persons consisting of a man and a woman twenty through fifty, a child six through eight, and a child nine through eleven years of age. The cost of the Thrifty Food Plan is the basis for the maximum allotment. Maximum food stamp allotments for various household sizes are computed in accordance with Section 3(o) of the Food Stamp Act which mandates that the cost of such diet be adjusted each October 1st to reflect 103 percent of the cost of the Thrifty Food Plan in the preceding June. It is this 3 percent adjustment that causes the difference between the Thrifty Food Plan and the maximum allotment.

Mr. DURBIN. Is the fiscal year 1995 budget request based on the Thrifty Food Plan or the maximum allotment level?

Mr. LUDWIG. The budget request is based on the maximum allotment level. The maximum allotment level as defined by law is 103 percent of the Thrifty Food Plan as of the preceding June, but, of course, the average food stamp recipient receives less than the maximum allotment. Therefore, in general terms, it is probably best to view the budget request as being based on our estimate of the average allotments expected times the estimated number of participants.

ERRONEOUS BENEFITS

Mr. DURBIN. Please explain why the overpayment error rate is projected to decrease from 7.8 percent in fiscal year 1994 to 7.6 percent in fiscal year 1995, but the amount of erroneous benefits increases.

Mr. LUDWIG. The amount of benefits issued erroneously increases slightly between Fiscal Year 1994 and Fiscal Year 1995 because the dollar value of total benefits issued is expected to rise faster than the overpayment error rate is expected to decline. The total dollar value of benefits issued is expected to rise over \$1 billion between 1994 and 1995. With this large increase in total benefits, the dollar value of benefits issued erroneously is expected to rise by \$27 million, despite the drop in the overpayment error rate.

PROGRAM COSTS

Mr. DURBIN. There is a net increase of \$5,242,000 in the appropriation request for other program costs including the effects of the Omnibus Reconciliation Act of 1993. Provide a brief description of all provisions in the Act that effect these program costs as well as the amount included in the request to implement the provision.

Mr. LUDWIG. No specific provision of the Act directly affected other program costs. However, with the exception of the provisions for the modifications of the QC system and the reduction of the enhanced match, all provisions affected program benefits. An increase

in program benefits results in increased costs for other program costs, printing food stamp coupons, the distribution, storage and delivery of coupons and the processing of coupons by the Federal Reserve Banks.

PRINTING COSTS

Mr. DURBIN. You are requesting an increase of \$1,239,000 in the appropriation for the printing of stamps. Please explain the need for this request when you are projecting a decrease in average participation in fiscal year 1995.

Mr. LUDWIG. Although we anticipate a decline in program participation, the increase requested for the printing of stamps is needed as a result of higher program benefit payments and the rate of inflation projected between Fiscal Years 1994 and 1995.

STATE EXCHANGE PROJECT

Mr. DURBIN. Describe, for the record, the State Exchange Project.

Mr. LUDWIG. State Exchange is a way for State agencies to improve their Food Stamp Program management by learning from one another. The project is based on the premise that often the most economical and efficient way for a State agency to find a solution to a management problem or to better manage some aspect of the program is to interact with another that has already successfully addressed the same concern. State Exchange Project funds are limited each year and are allocated based on the agencies priorities for the year. The priority for State Exchange is error reduction. During the past year State Exchange was used to enhance State awareness in the area of tax refund offset, payment accuracy, coupon trafficking, claims, quality control, and management evaluation teams.

Since its beginning in 1983 State Exchange has increased in funding from \$70,000 to the budgeted amount for Fiscal Year 1994 of \$369,000.

OUTREACH EFFORTS

Mr. DURBIN. Up to \$2.0 million of the amount available for research, evaluation; and demonstration projects will be used to test improved food stamp delivery to rural, elderly, and working people. What do you mean by working people?

Mr. LUDWIG. Working people are members of households with earnings who are eligible to participate in the Food Stamp Program. Historically, the working poor have lower Food Stamp Program participation rates than other groups. For example, households with earnings are less likely to participate in the Food Stamp Program than households participating in the Aid to Families with Dependent Children Program. As part of aiding the working poor, the Food Stamp Program is interested in testing ways to make participation more attractive to low-income workers.

NUTRITION EDUCATION

Mr. DURBIN. Also, up to \$2.75 million of these funds will be used to test better integration of nutrition in the Food Stamp Program. Please elaborate further on this proposal.

Mr. LUDWIG. There is a critical link between good diet and good health. While our country has a national nutrition policy embodied in the Dietary Guidelines for Americans, a gap exists between government policy and practice. This is nowhere more apparent than in the Food Stamp Program. This program can provide 27 million opportunities every month to affect lasting changes in nutrition and health for this generation and the next.

We are very interested in finding ways to increase the focus on nutrition in the Food Stamp Program. States are already responding to our interest, as demonstrated by the increase in State-planned nutrition activities, resulting in a Federal cost increase from \$2.2 million in Fiscal Year 1993 to approximately \$7.2 million in Fiscal Year 1994. However, this is a relatively small amount to spend on nutrition education in a program that will provide \$22.5 billion in benefits to low-income Americans in Fiscal Year 1994. To supplement our current efforts to improve the diets and, therefore, health of food stamp recipients, the Food and Nutrition Service (FNS) will design and test new ideas to improve the nutrition focus in the Food Stamp Program. Through these demonstrations, FNS hopes to identify effective methods for teaching recipients the value of good nutrition and its connection to good health.

Mr. DURBIN. Section 272.2(d)(2) of the Food Stamp Regulations allow States the option to develop nutrition education plans on a 50/50 administrative match provided the plans are conducted exclusively for the benefit of food stamp recipients. In fiscal year 1992, States spent about \$1.2 million on nutrition education activities. How much was spent in fiscal year 1993?

Mr. LUDWIG. In Fiscal Year 1993, States spent about \$2.2 million on nutrition education activities. It is projected that about \$7.2 million will be spent in Fiscal Year 1994.

In Fiscal Year 1994, 11 States have submitted nutrition education plans. To date, 10 States have nutrition education plans approved by Food and Nutrition Service and one (Vermont) is pending approval and is expected to be approved in the near future. Those States that have approved plans are: New York, North Carolina, Ohio, Minnesota, Wisconsin, Michigan, Missouri, New Hampshire, Washington and Oregon.

State nutrition education plans are designed to reach high risk and culturally diverse groups including senior citizens, homeless persons, teen mothers, persons with disabilities and battered women. The plans are targeted to both urban and rural populations and provide practical programs about general nutrition, special needs, food selection for nutrient density, food safety and sanitation, and food budgeting.

FOOD STAMP INCREASED COSTS

Mr. DURBIN. Last year the Administration proposed legislation to increase food stamp benefits by \$7.0 billion over four years to help offset the effects of the proposed energy tax on low-income households. As we all know the energy tax was not included in the final package, but an increase in food stamp benefits was. What was the level of this increase?

Mr. LUDWIG. The Mickey Leland Childhood Hunger Relief Act has a five-year, Fiscal Year 1994–1998, cost of \$2.5 billion. Most of

this increase in food stamp spending will benefit households with children. The major provisions of the Act include: removing the excess shelter expense deduction cap to allow families with children as well as other households to deduct high shelter costs from countable income, \$1,465 million; allowing the deduction of legally-binding child support payments to nonhousehold members to encourage low-income families to fulfill their child support obligations while ensuring that their current families will not be worse off, \$455 million; and increasing the Fair Market Value exclusion for vehicles, which expands Food Stamp Program eligibility to a number of low-income Americans, \$142 million.

Our budget request includes the cost of these provisions, with an expected increase in Fiscal Year 1995 of \$256 million.

DISASTER ASSISTANCE

Mr. DURBIN. Provide a table for the record showing the amount of disaster assistance provided to each State for fiscal years 1992 and 1993 and so far in fiscal year 1994.

Mr. LUDWIG. I will provide the information for the record.

[The information follows:]

DISASTER ASSISTANCE**Fiscal Year 1992**

STATE/DISASTER	FOOD STAMP BENEFITS	COMMODITIES	TOTAL
California/ Civil Unrest	\$ 2,207,716	\$ 2,000,000	\$ 4,207,716
Florida/ Hurricane Andrew	\$60,437,678	\$ 5,000,000	\$65,437,678
Louisiana/ Hurricane Andrew	\$13,156,235		\$13,156,235
Guam/ Typhoon Omar	\$12,226,855	\$ 275,000	\$12,501,855
Hawaii/ Hurricane- Iniki	\$ 4,218,031	\$ 500,000	\$ 4,718,031

Fiscal Year 1993

STATE/DISASTER	FOOD STAMP BENEFITS	COMMODITIES	TOTAL
Illinois/ MW Floods	\$ 1,463,031	\$ 605,000	\$ 2,068,996
Iowa/ MW Floods	\$ 1,839,550	\$ 240,000	\$ 2,079,550
Missouri/ MW Floods	\$ 5,642,261	\$ 683,000	\$ 6,325,261

Fiscal Year 1994

STATE/DISASTER	FOOD STAMP BENEFITS	COMMODITIES	TOTAL
California/ Earthquake	\$59,914,762	\$ 2,300,000	\$62,214,762

DISASTER ASSISTANCE

OUTLYING TERRITORY	VALUE OF COMMODITY ASSISTANCE
Fiscal Year 1992	
Federated States of Micronesia	\$3,300,000
Republic of the Marshall Islands	\$1,400,000

OUTLYING TERRITORY	VALUE OF COMMODITY ASSISTANCE
Fiscal Year 1993	
Federated States of Micronesia	\$ 700,000
Republic of the Marshall Islands	\$ 100,000

OUTLYING TERRITORY	VALUE OF COMMODITY ASSISTANCE
Fiscal Year 1994	
Federated States of Micronesia	\$ - 0 -
Republic of the Marshall Islands	\$ 110,000

WELFARE SIMPLIFICATION AND COORDINATION

Mr. DURBIN. The Welfare Simplification and Coordination Advisory Committee issued its final report on July 1, 1993. The report's primary recommendation is to replace the numerous programs that currently serve needy individuals with one family-focused, client-oriented comprehensive program. What is being done with the findings and recommendations of the Committee?

Mr. LUDWIG. To coincide with the release of the report, a press conference was held on June 29, 1993 to announce the completion of the report and to draw public attention to the need for greater conformity among assistance programs. In addition to the media, invitees included key Congressional leaders; the Secretaries of the Departments of Agriculture, USDA, Health and Human Services, HHS, Housing and Urban Development, HUD, and Labor, DOL; and staff from the White House Domestic Policy Council.

On June 30, 1993, a briefing was held at the Capitol to announce the findings of the Committee and its recommendations. Congressional staff, advocates, and public interest groups, such as the American Public Welfare Association, the National Governors Association, the National Association of Counties, and the National Association of State Legislatures, were invited.

Sammie Lynn Puett, Chair of the Advisory Committee, met with several Congressional leaders and Departmental officials to discuss the report. In addition, Advisory Committee members met with their State Representatives and Welfare Directors.

Over 1,400 copies of the report were distributed. Copies were provided to all members of the Congressional committees with jurisdiction over the four assistance programs examined by the Committee. These Committees are: the Senate Committee on Agriculture, Nutrition and Forestry; the Senate Committee on Finance; the Senate Committee on Banking, Housing and Urban Affairs; the House Committee on Agriculture; the House Committee on Ways and Means; the House Committee on Energy and Commerce; and the House Committee on Banking, Finance and Urban Affairs. The report was also sent to the Joint Committee on Reorganization of Congress.

Copies were provided to officials at USDA, HHS, HUD and DOL, State and local welfare agencies, public interest groups, advocates, and any interested party requesting a copy. The report was also provided to the White House Working Group on Welfare Reform.

The recommendations in this report are under consideration, along with other input, as the Administration develops its welfare reform proposal.

Mr. DURBIN. Please submit a copy of the final report for the record.

Mr. LUDWIG. A copy of the final report of the Welfare Simplification and Coordination Advisory Committee is submitted for the record.

[CLERK'S NOTE.—The report is too lengthy for reprint. A copy is retained in Committee files.]

WELFARE REFORM PROJECTS

Mr. DURBIN. Last year Mr. Braley submitted for the record a summary of all welfare reform projects the Department had under way. Would you please update this list to include new projects started in fiscal year 1993, projects planned for fiscal year 1994, and results of any projects that were completed.

Mr. LUDWIG. The Washington Family Independence Program, WFIP, is the only welfare reform demonstration for which we have final results. WFIP was designed to help families on welfare become self-sufficient. WFIP operated from July 1988 to June 1993 in 15 communities throughout Washington State.

WFIP provided financial incentives for education, training, and work; cashed out food stamps; expanded child care and other supportive services; provided transitional child care and Medicaid for a year after the family left welfare due to earnings; targeted services to pregnant and parenting teens; and developed a more client-oriented, family-focused service delivery system by implementing case coordination.

An evaluation conducted by the Urban Institute revealed that WFIP had little or no impact on participation in education or training by welfare clients. In fact, some participants in the treatment group showed reduced employment and average earnings, and increased likelihood of being on welfare. Evaluators also found that cashing out food stamps resulted in administrative cost savings, but clients' expenditures on food and the nutritional quality of food purchases were reduced. Cash-out reduced the stigma associated with receipt of food stamp benefits and allowed more budgetary flexibility to meet nonfood needs such as shelter and transportation. The program's most notable achievement was altering the "culture" of the local welfare office to emphasize better staff—client and interagency interactions.

Several factors may have contributed to the poor results of this demonstration. First, the pressures of cost neutrality altered the focus of WFIP resulting in program changes during the operation of the demo. Caseload growth due partially to poor economic conditions and the voluntary nature of the program, limited staff's ability to provide enhanced services. It is also believed that participants may not have understood the program well enough to take full advantage of all the available services.

I will submit for the record a chart showing all approved welfare reform demonstrations and those proposals under review by the Department.

[The information follows:]

Status of Food Stamp Welfare Reform Proposals

As of April 15, 1994

A - Asset Accumulation

N - Nutrition Education

T - Time-Limited AFDC Benefits

C - Cash-Out of Food Stamps

S - Special Saving Account

W - Wage Supplementation

<i>Under Review: 9</i>	<i>Summary</i>
<p>Connecticut Fair Chance</p> <p>T</p>	<p>Consists of three components - general reforms (no waivers required); Family Strength (incentives and support for working families with emphasis on child support); and Pathways (two year time-limited benefits and universal, mandatory JOBS Program). Family Strength will operate statewide; Pathways will operate in two-three sites. Demo will run for 7 years.</p>
<p>Georgia: The Fulton Project</p> <p>T</p>	<p>Provides nearly 1,000 jobs over a two-year period to Fulton County AFDC and food stamp recipients, as well as unemployed residents who do not receive public assistance. Freezes AFDC/food stamp benefits at entry into the demonstration; disregards earned income and resources for 12 months; provides food stamp recipients with a \$200 "cash support grant;" and imposes time-limited benefits: terminates AFDC and food stamp benefits after 12 months, even if the household remains eligible. Participation is voluntary. Will operate in one county for 2 years.</p>
<p>Maryland AFDC Welfare Reform Demonstration Research Project</p> <p>A C W</p>	<p>Rewards work and fosters self-reliance, responsibility, and family stability. Provides time-limited job preparation services, followed by mandatory work. Waivers include exclusion of one vehicle (with equity value up to \$5,000), increased resource limit, revised work requirements, exclusion of earnings of children, no increase in food stamps if AFDC is reduced due to sanction for noncompliance, cash-out of food stamps for wage supplementation, and a change to work registration exemptions. Will operate in two county offices and one site in Baltimore City for 3 years.</p>

<i>Under Review (cont'd)</i>	<i>Summary</i>
Michigan: To Strengthen Michigan Families- 1994 C T	Provides for 28 new initiatives (to be added to the current demonstration) that are based on 4 principles: encourage employment; target support; increase responsibility (time-limited assistance for noncompliant recipients); and involve communities. Waivers include: cash-out of food stamps for employed recipients; elimination of work registration exemptions; the exclusion of one vehicle; 25% reduction in benefits for noncompliance; and change in calculation of self-employment income. Will operate statewide .
Mississippi Work First Demonstration C W	Provides training-oriented jobs with private and public sector employers. AFDC and food stamp benefits will be replaced with a \$4.25/hour wage. Employers will contribute \$2/hour, of which \$1/hour will be placed in an Individual Development Account. Will operate in six counties for 3 years .
New York Child Assistance Program C	Extends the demo for an additional 5 years and expands operations into six additional upstate counties plus the borough of Brooklyn .
Oregon JOBS Plus C W	Substitutes private and public sector jobs for food stamp, AFDC and Unemployment Insurance benefits. Cash-out of food stamps. Will operate in six counties for 3 years .
Pennsylvania Pathways to Independence A C N S	Streamlines the eligibility process, supports families, enhances program equity, and provides positive incentives to encourage employment. Waivers include cash-out of food stamps for employed recipients, revision to the household definition, increase of the resource limit for employed recipients, elimination of the gross income test, exclusion of one vehicle, and exclusion of special accounts for retirement and education . Demo will be limited to 1,000 participants in one or more counties for 5 years .
South Dakota: Strengthening South Dakota's Families Initiative T	Offers time-limited benefits with provisions designed to increase parental responsibilities, reduce long-term dependency on welfare, and encourage employment. Excludes income and resources and provides for the sanction of the entire household for quitting a job without good cause. Will operate statewide for 5 years .

<i>Approved: 15</i>	<i>Summary</i>
Alabama Avenue to Self-Sufficiency through Employment and Training C	Consolidates AFDC, Food Stamp, and Medicaid Programs. Cash-out of food stamps, case management, standardized benefits, intensified employment and training activities, enhanced child support enforcement, and extended Medicaid eligibility. Operates in three counties for 5 years .
Colorado Personal Responsibility and Employment Program C N T	Requires active participation by clients in education, skills training, preventative health care, and employment opportunities. Waivers include: cash-out of food stamps and consolidation with AFDC and child care benefits. Time-limited benefits for employable adult AFDC recipients who are not employed (30 hours per week) or actively participating in JOBS two years after entering JOBS under the demonstration. Operates in five counties for 5 years .
Florida Family Transition Program T	Provides time-limited benefits , intensive case management, and incentives for obtaining and retaining employment. Will operate in two counties for 8 years .
Iowa Family Investment Program A S	Provides a transition to work, an increase in family stability, and the development of a new social contract between recipients and government. Excludes certain income and allows the accumulation of assets up to \$5,000 per household. Operates statewide for 5 years .
Maryland Primary Prevention Initiative	Encourages increased parental responsibility and preventative health care. Excludes as income an annual \$20 special need allowance that is provided to household members who receive an annual check-up. Operates statewide for 5 years .

<i>Approved (cont'd)</i>	<i>Summary</i>
Michigan: To Strengthen Michigan Families	Expands eligibility to working and two-parent families, modifies work requirements and strengthens child support provisions. Excludes as both income and resources all income earned by dependent children, up to age 19, who are AFDC recipients and attending school. Operates statewide for 5 years .
Minnesota Family Investment Plan C	Consolidates AFDC, General Assistance, and food stamps to form a single program with one set of rules. Cash-out of food stamp benefits. Will operate in seven counties for 5 years .
Missouri Beyond Welfare (21st Century Communities Demonstration) A C W	Food stamp benefits are cashed out and consolidated with AFDC to form a wage pool for supplemented jobs for public assistance cases. Also increases the resource limit to \$10,000 for individuals participating in subsidized jobs. Will operate in up to 20 communities for 12 years .
New York Child Assistance Program C	Provides assistance to AFDC recipients with earnings and child support orders. In place of AFDC, recipients receive child assistance payments based on household size and earned income. Cash-out of food stamp benefits. Operates in seven counties for 5 years .
Ohio Transition to Independence	Provides assistance to AFDC recipients for self-sufficiency through employment. Excludes as income incentive payments made to AFDC recipients who meet school attendance requirements under the Learning, Education, and Parenting (LEAP) Demonstration, and allows the State to develop a standard deduction for self-employed business expense of in-home day care providers. Operates statewide for 5 years .

<i>Approved (cont'd)</i>	<i>Summary</i>
<p>Utah Single Parent Employment Demonstration Program</p> <p>C</p>	<p>Targets AFDC recipients with intensive work requirements. Participants who complete assigned activities receive incentive payments; those who are noncompliant receive reduced AFDC benefits. Optional cash-out for public assistance households. Exclude educational income; exclude up to \$8,000 in total equity value for one vehicle and continue exclusion for one year after AFDC is terminated; excludes from income diversion payments and \$90 of AFDC grant for each person engaged in full-time self-sufficiency activities; increase change reporting amount from \$25 to \$50 per month for PA cases for up to one year after AFDC is terminated; and allow State to determine which eligibility factors to verify for up to one year after the household leaves AFDC. Operates in three counties for 5 years.</p>
<p>Vermont Family Independence Project</p> <p>A T W</p>	<p>Encourages short-term transitional assistance by expanding work requirements and removing barriers to employment. Time-limited benefits if not employed or working in subsidized community service jobs. Exclude one vehicle and count equity value of other vehicles; exclude accumulated assets previously counted as income; exclude as income incentive payments made to AFDC parents for completing parenting classes or other approved activities; and waive food stamp work or voluntary quit disqualifications when household is sanctioned under AFDC program for failing to meet the demonstration's work requirements. Will operate statewide for 7 years.</p>
<p>Virginia Incentive to Advance Learning</p>	<p>Targets AFDC families of children in grades six, seven, and eight in three schools. Provides incentives to encourage school attendance and extensive counseling services. Excludes the AFDC incentive payments as income. Operates in one county and two cities for 2 years.</p>

<i>Approved (cont'd)</i>	<i>Summary</i>
<p>Virginia Welfare Reform Demonstration Pilot</p> <p>A S</p>	<p>Pilot: Will establish a partnership among State businesses and long-term AFDC recipients to place 600 initial recipients into self-sustaining employment which pays \$15,000-\$18,000 annually so they can become and remain self-sufficient. Employer will make up-front commitment to hire the recipient upon completion of training (not to exceed one year). All income and resources will be excluded for pilot participants during the training period, including child support; first vehicle will be excluded from resources. Operates statewide for 4 years. Waiver also approved for entire caseload to allow recipients to accumulate up to \$5,000 for use in educational activities or down payment on a home.</p>
<p>Wisconsin Work Not Welfare</p> <p>C N T</p>	<p>Replaces welfare with time-limited benefits (24 months), immediate and universal participation obligation, and a focus on self-sufficiency and work. Cash-out of food stamps; income averaging over the 6-month certification period; nutrition education; and agreement to actively explore Electronic Benefit Transfer as an alternative to cash-out. Operates in two counties for 11 years.</p>

LIABILITIES

Mr. DURBIN. In fiscal year 1992, twelve State agencies were notified of potential liabilities totalling \$258.5 million. As a result of the Mickey Leland Childhood Hunger Relief Act these liabilities were revised to \$117.1 million. What is the status of these liabilities?

Mr. LUDWIG. On August 11, 1993, the Food and Nutrition Service (FNS) notified the 12 State agencies of the effect of the Mickey Leland Childhood Hunger Relief Act on the potential liabilities for Fiscal Year 1992. FNS will not assert a formal claim against these States until appropriate rulemaking has occurred. The potential liabilities against California (\$658) and Iowa (\$657) were waived based upon a determination that pursuit of these small claims is not in the best interest of the Food Stamp Program.

In addition, on January 19, 1994, FNS and the Florida State agency signed an agreement to settle its Fiscal Year 1992 potential liability of \$98,766,685 and a projected Fiscal Year 1993 liability. Under the terms of the settlement agreement, the Florida State agency will reinvest a minimum of \$16.5 million and a maximum of \$23.5 million in program operational improvements specifically designed to reduce errors measured by the quality control system over the next five years. As a result of this settlement agreement, the potential liabilities for Fiscal Year 1992 for the remaining nine States has been reduced to \$18,328,934.

STAGGER FOOD STAMP ISSUANCE

Mr. DURBIN. Public Law 103-11 delayed until January 31, 1994 the implementation of a requirement to stagger food stamp issuance for families living on Indian reservations and included a prohibition against requiring such households to report monthly on household circumstances. What was the reason for this delay and what impact will it have on the program?

Mr. LUDWIG. In addition to the delay resulting from Public Law 103-11, Public Law 103-205, enacted December 17, 1993, further delayed implementation until March 15, 1994. The basic reason for delayed implementation of these provisions is that subsequent to their insertion into the 1990 Farm Bill, Food, Agriculture, Conservation, and Trade Act of 1990, enacted November 28, 1990, Congress became aware that State food stamp administrators had serious concerns about these provisions. To address those concerns, Congress continued to delay implementation of the provisions while it gathered additional information about the problems facing households and food stamp administrators on Indian reservations. At this point, Congress has modified these two provisions, P.L. 103-225. The March 11, 1994 Congressional Record, pages S2905-S2908, provides detailed information concerning the history of these provisions. The legislation was signed by the President on March 25, 1994.

We will work with affected State agencies to successfully implement the law.

NATIONAL VOTER REGISTRATION ACT

Mr. DURBIN. Public Law 103-31, the National Voter Registration Act of 1993 requires that all State offices that provide public assistance must distribute mail voter registration application forms and assist applicants in completing the forms unless such assistance is refused. The Act also requires these offices to accept applications for transmittal to the appropriate State election official. This Act becomes effective on January 1, 1995. What impact will this have on the program?

Mr. LUDWIG. The Administration supports the objectives of the National Voter Registration Act. FNS will provide assistance as requested and as appropriate to the State agencies. The primary contact for public assistance offices for voter registration guidance and procedures will be State election officials. FNS will also provide matching funds for voter registration activities in public assistance offices in accordance with cost allocation plans for designating costs associated with the programs administered by those offices. Implementation of the National Voter Registration Act is expected to have a minimal impact on the Food Stamp Program.

ERROR RATES

Mr. DURBIN. Please update the table that appears on page 334 of last year's hearing record showing the overpayment error rate, the underpayment error rate, and the total error rate to include fiscal year 1992 and estimates for fiscal year 1993.

Mr. LUDWIG. Fiscal Year 1993 official error rates are not available until June 30, 1994. However, preliminary estimates indicate that Fiscal Year 1993 error rates will not be lower than the Fiscal Year 1992 error rates. The overpayment, underpayment and total error rate for Fiscal Years 1988 through 1992 will be submitted for the record.

[The information follows:]

Fiscal year	Overpayment rate	Underpayment rate	Total
1988	7.41	2.52	9.93
1989	7.27	2.54	9.82
1990	7.35	2.47	9.82
1991	6.96	2.35	9.30
1992	8.19	2.50	10.69

Mr. DURBIN. Also, provide an update of the table that appears on the same page showing the overpayment error rate, the dollar amount associated with this rate, and the amount recovered to include fiscal year 1992 and estimates for fiscal year 1993.

Mr. LUDWIG. Estimates for Fiscal Year 1993 are not available. The updates on the overpayment error rate, including Fiscal Year 1992 data, will be submitted for the record.

[The information follows:]

Fiscal year	Overpayment error rate (percent)	Estimated overpay- ment	Recovered (claims collected)
1980	9.51	\$791,082,618	\$0
1981	9.90	1,013,137,756	1,372,228.00
1982	9.54	905,764,366	2,898,386.00

Fiscal year	Overpayment error rate (percent)	Estimated overpay- ment	Recovered (claims collected)
1983	8.32	894,504,311	1,058,131.20
1984	8.59	902,320,084	588,503.00
1985	8.27	847,502,397	299,390.00
1986	8.09	840,024,012	10
1987	7.58	742,792,841	10
1988	7.41	825,622,613	10
1989	7.27	849,249,362	10
1990	7.35	1,036,960,425	10
1991	6.96	1,206,775,325	147,411.00
1992	8.19	1,711,896,360	20
Total		12,567,632,470	6,264,049.20

¹ States have agreed to invest almost \$45 million in program improvements as a result of settling \$300 million in outstanding quality control liabilities for Fiscal Years 1986-1991. Because it is an investment of State funds, it is not included in the dollar value of claims recovered. The \$47,411 represents a cash payment by the three States which chose to pay the settlements as opposed to investing in program improvements.

² On January 19, 1994, FNS and the Florida State agency signed an agreement to settle its Fiscal Year 1992 potential liability of \$98,766,685 and a projected Fiscal Year 1993 liability of \$56,058,052. Under the terms of the settlement agreement, the Florida State agency will reinvest a minimum of \$16.5 million and a maximum of \$23.5 million in program operational improvements specifically designed to reduce errors measured by the quality control system over the next five years.

Mr. DURBIN. Update the table that appears on page 290 of last year's hearing record showing the states and the amount of enhanced funding each received for low-error rates to include fiscal years 1992 and 1993.

Mr. LUDWIG. In 31 instances, States received up to 10 percent enhanced administrative funding totalling \$34,407,085 for achieving low error rates during Fiscal Years 1986 through 1992. Data for Fiscal Year 1993 is not included since the qualifying States and amounts for this and subsequent years will not be known until nine months after the year for which they qualify.

A list of the States and amounts received by fiscal year will be submitted for the record.

[The information follows:]

Fiscal year	Number of States	States	Total enhanced funding
1986	3	Nevada	475,328
		North Dakota	358,452
		South Dakota	341,226
1987	4	Hawaii	1,012,452
		Nevada	511,258
		North Dakota	328,001
		South Dakota	321,744
1988	2	Nevada	560,703
		South Dakota	425,259
1989	7	Alabama	459,274
		Hawaii	909,546
		Kentucky	4,485,273
		Montana	248,314
		Nevada	578,338
		North Dakota	95,466
		South Dakota	373,931
1990	5	Alabama	905,586
		Hawaii	1,095,531
		Kentucky	4,274,224
		North Dakota	51,530
		South Dakota	609,745
1991	5	Alabama	3,836,425
		Hawaii	1,344,323
		Kentucky	3,382,804
		North Dakota	217,963
		South Dakota	640,849

Fiscal year	Number of States	States	Total enhanced funding
1992	5	Hawaii	1,411,896
		Kentucky	4,492,878
		North Dakota	56,654
		South Dakota	499,799
		Virgin Islands	102,313
Totals	31		34,407,085

BARRED RETAILERS

Mr. DURBIN. How many retailers were barred from the program in fiscal year 1993?

Mr. LUDWIG. For Fiscal Year 1993, the number of retailers that were disqualified is 842, and the number of retailers that were withdrawn is 4,402. FNS does not keep track of the number of stores whose applications for participation were denied.

RECIPIENT CLAIMS

Mr. DURBIN. Update the table that appears on page 333 of last year's hearing record showing the total amount of recipient claims and the actual amount collected to include fiscal year 1993 actuals and fiscal year 1994 estimates.

Mr. LUDWIG. I will provide the information in table form for the record.

[The information follows:]

FOOD STAMP RECIPIENT CLAIMS

[Dollars in millions]

	1988	1989	1990	1991	1992	1993	1994
Amount of claims established	\$181	\$197	\$193	\$216	\$223	\$245	\$258
Amount of claims collected	71	73	84	94	109	117	126

Note: Figures for 1994 are estimates.

PARTICIPATION AND UNEMPLOYMENT RATES

Mr. DURBIN. Also update the table that appears on page 335 of last year's hearing record showing food stamp participation and unemployment rates to include fiscal year 1993 actuals and fiscal year 1994 estimates.

Mr. LUDWIG. The information requested will be submitted for the record.

[The information follows:]

HISTORICAL FOOD STAMP DATA—AVERAGE MONTHLY PARTICIPATION AND UNEMPLOYMENT RATE

Fiscal year	Participants	Civilian unemployment rate (percent)
1982	21,717,398	9.7
1983	21,624,639	9.6
1984	20,853,631	7.5
1985	19,899,052	7.2
1986	19,429,101	7.0
1987	19,113,128	6.2
1988	18,644,192	5.5
1989	18,806,463	5.3

HISTORICAL FOOD STAMP DATA—AVERAGE MONTHLY PARTICIPATION AND UNEMPLOYMENT RATE—Continued

Fiscal year	Participants	Civilian unemployment rate (percent)
1990	20,066,750	5.5
1991	22,624,627	6.7
1992	25,405,615	7.4
1993	26,982,399	¹ 7.0
1994	27,394,000	² 6.6

¹ Unemployment Rate from the 12/93 OMB Assumption Set.

² Participation and Unemployment for Fiscal Year 1994 are estimates.

STREET TRAFFICKING INITIATIVE

Mr. DURBIN. What is the status of the pilot projects you planned for fiscal year 1994 to identify effective detecting investigative and sanctioning techniques against street trafficking?

Mr. LUDWIG. We originally planned to fully fund the pilot projects, however, without a specific appropriation for the projects, the Agency was not able to provide 100 percent funding through its existing resources. Nevertheless, California has decided to move forward with its street trafficking effort with matching funds from the Food and Nutrition Service.

The California Department of Social Services will conduct investigations focusing on the recipient, buyer and retailer who participate in the illegal sale of food stamps. The project is to begin in Los Angeles County and the San Francisco Bay area over the next few months.

P.L. 103-225 authorized the Agency to spend up to \$4 million in Fiscal Year 1995 for street trafficking projects conducted by States. It is uncertain whether the Agency can fund this effort within our Fiscal Year 1995 request because our discretionary funds had been allocated prior to enactment of P.L. 103-225.

NUTRITION ASSISTANCE FOR PUERTO RICO

Mr. DURBIN. Costs of the Nutrition Assistance Program for Puerto Rico during fiscal year 1993 were \$58.41 per person per month for benefit costs, and \$1.69 per person per month for administrative costs. How do these costs compare to the Food Stamp Program?

Mr. LUDWIG. Food Stamp Program benefit costs for Fiscal Year 1993 averaged \$67.96 per participant per month, and the Federal share of administrative costs for this same period averaged \$4.79 per participant per month.

SPECIAL WAGE INCENTIVE PROGRAM

Mr. DURBIN. Please update the table that appears on page 342 of last year's hearing record showing the costs of the Special Wage Incentive Program to include fiscal year 1992 and 1993 actuals and fiscal year 1994 estimates.

Mr. LUDWIG. The information requested will be submitted for the record.

[The information follows:]

Fiscal year	Administrative costs	Benefit costs	¹ Total
1988	0	0	0
1989	32,206	68,769	100,975
1990	55,464	616,616	672,080
1991	238,292	2,490,138	2,728,430
1992	643,366	8,839,521	9,482,887
1993 ²	1,092,646	13,316,429	14,409,075
1994 ³	1,131,660	32,311,045	33,442,705

¹ Federal share of program costs.

² Preliminary figures.

³ Budgeted amount.

CARRYOVER BALANCE

Mr. DURBIN. You are proposing to carryover \$31,163,000 from fiscal year 1994 into fiscal year 1995. Why is there such a large unobligated balance proposed to be available at the end of fiscal year 1994?

Mr. LUDWIG. The estimates of large year-end carryover in the Food Distribution Program on Indian Reservations, FDPIR, is the result of several factors. Participation in FDPIR has declined significantly over the last 5 years. Since Fiscal Year 1989, participation has decreased from approximately 138,000 to about 112,000 in Fiscal Year 1993. Despite the decline, appropriations did not begin to decrease appreciably until Fiscal Year 1994. The decline in participation, coupled with the over-ordering of commodities, resulted in accumulation of inventories in excess of program needs.

NUTRITION EDUCATION

Mr. DURBIN. In fiscal year 1994, FNS specifically earmarked some Food Distribution Program on Indian Reservation, FDPIR, administrative funds for nutrition education. How much was actually earmarked? Describe how these funds were used? Was any matching funds provided by the Reservation? How much will be allocated in fiscal year 1995 for these activities?

Mr. LUDWIG. FNS earmarked \$150,000 for nutrition education in Fiscal Year 1994.

These funds were made available to FNS regional offices based on each region's allocation of general Food Distribution Program on Indian Reservations, FDPIR, administrative funds as a percentage of total funds allocated. The funds could be used by FNS regional offices either to purchase nutrition education materials/services for Indian Tribal Organizations (ITOs) and State agencies, or to provide competitive grants to ITOs. Although some of the funds are being used by the ITOs to travel to regional offices to receive nutrition education training and to buy nutrition education materials, the majority of the funds are being utilized by the ITOs to develop innovative approaches to delivering nutrition education. Some of these projects include: conducting demonstrations and workshops for participating households on how to use commodities to stretch their food dollars and prepare healthy meals; producing videos to increase awareness regarding the relationship between diet and health; and recruiting and training volunteers about the role of proper nutrition so that they, in turn, can work with participating households. ITOs will submit project evaluations to FNS.

The reservations were not required to match any portion of their nutrition education grants.

In the Fiscal Year 1995 budget, \$1 million is requested to train and hire Native American nutrition education aides on participating reservations. Some of the funds will also be used to evaluate the efficacy of the nutrition education effort so that we will be more certain how best to provide effective nutrition education in the future.

Mr. DURBIN. What is the level of funding currently provided for nutrition aides to provide nutrition education for FDPIR recipients? How many nutrition aides are currently being funded? How many additional aides will this increase provide for?

Mr. LUDWIG. None of the funding in the Fiscal Year 1994 appropriation earmarked for nutrition education is being used for this purpose. Some small portion of the general program administrative grants which Indian Tribal Organizations (ITOs) receive may be funding a small number of nutrition education aides in the largest ITOs. However, as a rule nutrition education competes with other administrative needs, such as household certification, food warehousing, and monthly benefit issuance. Therefore, the nutrition education set-asides were established.

While the Department believes that nutrition education can be effectively imparted through a variety of approaches, it strongly supports the training and hiring of indigenous nutrition education aides. In Fiscal Year 1992, the Food and Nutrition Service funded two aides on the Wind River Reservation in Wyoming. They underwent intensive training by the Extension Service's Expanded Food and Nutrition Education Program within the county. These aides then provided nutrition counseling in the homes of participants, conducted nutrition workshops in schools, and engaged in other nutrition education activities that entail direct, personal contact with participants. This approach produced dramatic results. For example, some diabetics who controlled the disease through medication now control it through diet. Given the high incidence of deeply entrenched diet-related health conditions such as diabetes, hypertension, and obesity among Native Americans, the direct, intensive nutrition education that well-trained aides can provide represents the best chance to make basic changes in the diet of this population that will result in improved health. Currently, diet-related health conditions are largely addressed through treatment, after they have developed. The preventive approach of nutrition education has great potential to reduce health care costs, and thus to more than pay for itself.

The \$1 million requested would fund between 70 and 80 aides working 30 hours per week. The funds would also support: The development of a training curriculum that is culturally sensitive to Native Americans and focuses on their major diet-related health conditions; conduct of training; and quality control and evaluation systems.

Mr. DURBIN. In Fiscal Year 1993, \$135,000 in FDPIR funds was made available to either purchase nutrition education publications and materials for Indian Tribal Organizations, ITOs, and State agencies or to provide competitive grants to ITOs. How was this funding used?

Mr. LUDWIG. In Fiscal Year 1993, the \$135,000 earmarked specifically for nutrition education was made available for FNS regional offices to purchase nutrition education publications and materials for Indian Tribal Organizations ITOs and State agencies, or provide competitive grants to ITOs. This small amount of money, most of which was awarded to ITOs, supported 17 different nutrition education projects, such as seminars on preparing healthy meals. A copy of the specific project summaries is available upon request. The cost of the projects ranged from \$600 to \$24,065. The grants have stimulated innovation and are supporting a wide variety of cultural approaches to nutrition education.

Mr. DURBIN. What was the level of funding for this purpose in fiscal year 1994?

Mr. LUDWIG. In Fiscal Year 1994, the Food and Nutrition Service earmarked \$150,000 for nutrition education in accordance with the President's Fiscal Year 1994 budget.

PARTICIPATION LEVELS

Mr. DURBIN. Update the table that appears on page 346 of last year's hearing record showing FDPIR participation levels to include fiscal year 1993 actuals and fiscal year 1994 estimates.

Mr. LUDWIG. I will submit this information for the record.
[The information follows:]

FDPIR participation levels—average monthly participation

Fiscal year:	<i>Persons</i>
1986	144,952
1987	145,679
1988	137,771
1989	141,152
1990	138,313
1991	129,629
1992	117,645
1993	115,801
1994	116,399

Note: This table includes participation in the former Trust Territories (3,980 in FY 93; 4,000 in FY 94).

Source of FY 93 data: "Program Information Report: January 1994", published 3/24/94. FY 94 estimate—"Green Sheets", p. 31-60.

NEW TRIBES IN PROGRAM

Mr. DURBIN. Were any new tribes accepted into the program in fiscal year 1993?

Mr. LUDWIG. No new tribes joined the program as an administering agency. However, the Puyallup Tribe of Washington, with a program participation of approximately 350, was admitted to the program under the Small Tribes of Western Washington, a currently participating administering agency.

REQUESTS TO PARTICIPATE

Mr. DURBIN. Are there any tribes requesting participation into the program in fiscal year 1994?

Mr. LUDWIG. Yes. The Yurok Tribe, located in California, has applied for participation in the program. The Tribe is currently undergoing a capability review to determine if it is able to administer the program. Estimated participation is 800. If found administra-

tively capable, the tribe is expected to begin participating in the program in Fiscal Year 1995.

ELDERLY FEEDING PARTICIPATION

Mr. DURBIN. Please update the table that appears on page 346 of last year's hearing record showing participation levels for the elderly feeding program to include fiscal year 1993 actuals and fiscal year 1994 estimates.

Mr. LUDWIG. In Fiscal Year 1993, the Nutrition Program for the Elderly served 244,268,249 meals. As reflected in the President's Budget, it is estimated that approximately 244 million meals will be served in Fiscal Year 1994. I will submit a table for the record. [The information follows:]

NPE meals served—annual totals

Fiscal year:	Meals
1986	228,244,565
1987	232,128,489
1988	240,421,065
1989	243,333,821
1990	245,621,160
1991	244,597,713
1992	245,441,307
1993	244,268,249
1994 (estimate)	243,950,000

FREELY ASSOCIATED STATES AND PALAU

Mr. DURBIN. Update the table that appears on page 348 of last year's hearing record showing the amount of funds made available to the Freely Associated States and Palau to reflect fiscal year 1993 actuals and fiscal year 1994 estimates.

Mr. LUDWIG. I will provide the information for the record. [The information follows:]

FUNDS AVAILABLE TO THE FREELY ASSOCIATED STATES, PALAU AND AMERICAN SAMOA

	Freely Associ- ated States	Palau	American Samoa	Total
Fiscal Year				
1994 ¹	\$581,000	\$446,000	\$2,700,000	\$3,727,000
1993	581,000	437,000	0	1,018,000
1992	527,000	311,000	0	838,000
1991	421,000	558,000	0	979,000
1990	421,000	589,000	0	1,010,000
1989	461,000	69,000	0	530,000
1988	501,000	263,000	0	764,000
1987	1,596,552	0	0	1,596,552

¹ Includes \$2.7 million for American Samoa (initial year of inclusion).

AUTHORIZATION STATUS

Mr. DURBIN. What is the status of the authorization for this program?

Mr. LUDWIG. Bikini, Utrik, Rongelop, and Entowok in nuclear-affected zones will continue to receive United States Department of Agriculture (USDA) commodities and administrative funds through Fiscal Year 1997, as authorized by P.L. 102-247, enacted February 24, 1992. To continue this program into the current fiscal year, \$581,000 of the 1994 appropriation is supporting the program. The

former Trust Territories that ratified the Compact of Free Association continue to be eligible for emergency assistance from the Department for a 15-year period after implementation of the Compact pursuant to the Disaster Relief Act. Until the Compact of Free Association for Palau is implemented, Palau continues to receive assistance under normal program rules.

FOOD BANK AND SOUP KITCHEN REVIEWS

Mr. DURBIN. States are responsible for ensuring that soup kitchens and food banks comply with all Federal program regulations and requirements. How often do States examine the procedures of soup kitchens and food banks for compliance? What kind of oversight does the Department provide?

Mr. LUDWIG. Federal regulations mandate that States perform an on-site review of Soup Kitchens and Food Banks at least once every 4 years.

Regarding Federal program oversight, in Fiscal Year 1992, Food and Nutrition Service Headquarters and Regional Offices began development of Comprehensive Management Evaluation Guidance for all Food Distribution Programs in order to facilitate effective reviews and appropriate technical assistance to States. While guidance has been completed and is in use for six of ten programs, guidance for the review of Soup Kitchens and Food Banks is currently under development. The guidance will help regional offices to conduct comprehensive management evaluations in a manner that is uniform from region to region. However, while the guidance provides the necessary tools to complete a thorough review, limited staffing and travel resources prevent the conduct of management evaluations at the frequency and depth necessary to ensure effective, efficient, and compliant program management by States.

CHARITABLE INSTITUTIONS

Mr. DURBIN. Surplus commodities are donated to nonprofit charitable institutions serving needy persons and to summer camps for children. In fiscal year 1993, this amounted to almost \$99 million worth of commodities. What is the level of donations for fiscal year 1994? Are you proposing to change this level during fiscal year 1995?

Mr. LUDWIG. The distribution of USDA commodities acquired through the Commodity Credit Corporation's price-support activities to charitable institutions and summer camps is not a program supported by its own separate appropriation. Rather, commodities are provided to States through broad legislative authority that permits their distribution to a wide variety of institutions serving needy persons, including charitable institutions and summer camps. These price-support commodities are generally available for distribution only when they cannot be sold.

For Fiscal Year 1993, the Agricultural Stabilization and Conservation Service ASCS committed to making \$54.0 million in earmarked purchases of grains, rice, pasta, peanut products, and vegetable oils for charitable institutions and summer camps. However, these outlets actually ordered only \$44.0 million of that amount, in addition to \$40.7 million in "bonus" commodities (butter and cornmeal).

For fiscal year 1994, the Department has committed to providing bonus commodities and up to \$53.3 million is earmarked purchases for charitable institutions and summer camps. Year-to-date, \$20.0 million in bonus commodities, and \$31.8 million in the earmarked commodities, have been ordered by these outlets. It remains to be seen at this point whether these outlets will order commodities up to the earmarked limit this fiscal year.

Because of the distribution of these commodities, as well as changes in price-supported legislation, the inventories of commodities available for donation have been greatly reduced. Therefore, in fiscal year 1995, USDA will be unable to provide earmarked purchases to charitable institutions and summer camps; only butter will be available. The President's budget requests an increase of \$10 million for the Soup Kitchen/Food Bank Program. Such organizations which participate both in the Soup Kitchen/Food Bank Program and as charitable institutions will receive in the aggregate slightly more commodity support than they did in fiscal year 1993.

INCOME ELIGIBILITY FOR TEFAP

Mr. DURBIN. What are the income eligibility criteria used for participants in the program: How are these criteria enforced and monitored?

Mr. LUDWIG. States are responsible for establishing income-based eligibility criteria for the Emergency Food Assistance Program, TEFAP. These criteria range from 125 percent to 185 percent of the annual Federal Income Poverty Guidelines. States may also permit households to be "categorically" eligible for TEFAP based on their participation in other assistance programs which use income as a means of determining eligibility, such as Aid to Families with Dependent Children and food stamps.

States are also responsible for monitoring the operation of TEFAP. Implementation of established eligibility criteria by mass distribution sites and food pantries is monitored by States through on-site reviews. Federal regulations require that States conduct an annual review of all emergency feeding organizations within the State; and an annual review, to be conducted simultaneously with actual distribution and/or eligibility determinations, of one-third or 50, whichever is fewer, of all distribution sites within the State.

MANDATED TEFAP DEMONSTRATION PROJECTS

Mr. DURBIN. Public Law 103-66, the Omnibus Budget Reconciliation Act of 1993, provided \$230,000 in mandatory funds to operate demonstration projects in two State during each of the fiscal years 1994 through 1996. The projects are designed to test commodities that are low in sodium, fat, sugar, and are high in nutrients. Provide a brief description of each project that is being funded in fiscal year 1994 including the funding level and the State that is operating the project.

Mr. LUDWIG. The Omnibus Budget Reconciliation Act of 1993 both authorizes and appropriates a total of \$230,000 for each of fiscal years 1994 through 1996 for the demonstration project. The annual appropriation provides \$110,000 per State for Department of Agriculture commodity purchases and \$5,000 to each State for project administration and evaluation. Because the authorizing leg-

isolation also provides automatic funding for the out years, funding for the projects is not included in the President's fiscal year 1995 request. The two States selected for project participation are Vermont and Kentucky. After soliciting input from both States, the Department selected and purchased macaroni, ready-to-eat corn chex, and canned tuna for distribution in fiscal year 1994. These commodities will be distributed in addition to those currently made available through the Emergency Food Assistance Program. Deliveries are expected during the third and fourth quarters. States are required to submit project evaluations in accordance with evaluation plans outlined in their proposals by December 15, 1994.

Mr. DURBIN. Will these projects receive additional funding in fiscal year 1995?

Mr. LUDWIG. Section 18962 of The Omnibus Budget Reconciliation Act of 1993, Public Law 103-66, both authorizes and appropriates a total of \$230,000 for each of the fiscal years 1994 through 1996 for the Emergency Food Assistance Program Demonstration Project. These funds are to be paid to the Department from the Department of Treasury out of any funds not otherwise appropriated. When Congress enacted this legislation, it authorized and appropriated \$230,000 for each of the 3 years the project is to be implemented. Consequently, the Department has not submitted a budget request for fiscal year 1995.

PROCESSING OF COMMODITIES

Mr. DURBIN. USDA pays for the processing of commodities into household size packages. How much was spent on this activity during fiscal year 1993? How much do you anticipate spending in fiscal year 1994?

Mr. LUDWIG. On an ongoing basis, USDA purchases commodities in family sized packages for the Commodity Supplemental Feeding Program, Food Distribution Program on Indian Reservations, the Emergency Food Assistance Program, and the Soup Kitchen/Food Bank Program.

The commodities are purchased through invitations issued by the Agricultural Marketing Service, which stipulates appropriate family sized packs. The cost of the commodity and packaging are included in the purchase price.

TEFAP COMMODITIES

Mr. DURBIN. Update the table that appears on page 343 of last year's hearing record showing the amount of commodities purchased with appropriated funds and the amount of commodities donated to the program to include fiscal year 1993 actuals and fiscal years 1994 and 1995 estimates. Also, add two additional columns to reflect the quantity, in pounds, that this amount supports.

Mr. LUDWIG. An updated chart showing the pounds and value of commodities purchased with appropriated funds and the pounds and value of commodities donated to the TEFAP in fiscal years 1993 and 1994 will be submitted for the record.

The Budget request does not include funds for purchasing TEFAP commodities for fiscal year 1995. At this time, butter is the only commodity that will be available to TEFAP as a bonus com-

modity, and orders cannot exceed 6 million pounds per month in Fiscal Year 1995.

[The information follows:]

TEFAP COMMODITIES

Year	Entitlement		Bonus	
	Pounds	Value	Pounds	Value
1982			121,682,012	\$179,460,730
1983			754,034,303	971,954,427
1984			856,348,140	1,034,156,353
1985			929,562,429	973,110,714
1986			947,692,348	845,794,765
1987			1,014,088,662	845,778,720
1988			693,486,404	537,335,272
1989	140,732,700	\$119,977,167	276,026,814	135,374,656
1990	148,006,284	119,017,514	262,920,772	118,996,793
1991	177,844,572	119,198,359	234,080,760	88,563,131
1992	159,347,682	119,305,477	239,041,044	84,779,276
1993	288,677,173	161,227,078	110,750,630	63,324,846
1994	179,831,661	79,096,000	120,000,000	66,449,552
1995	0	0	72,000,000	59,817,600

Mr. DURBIN. What bonus commodities do you plan to distribute to the program in the fiscal year 1994?

Mr. LUDWIG. Butter and cornmeal are being offered during fiscal year 1994.

ADMINISTRATIVE FUNDS

Mr. DURBIN. Please update the table that also appears on page 343 of last year's hearing record showing the amount of administrative funds returned to the U.S. Treasury to include fiscal year 1993.

Mr. LUDWIG. The updated table will be provided for the record, however, with the advent of the National Defense Authorization Act for Fiscal Year 1991, Public Law 101-510, we are now required to maintain the balance of unobligated funds on our accounting records. Therefore, funds are no longer returned to Treasury until after they expire in the fifth year following their appropriation. Prior to their expiration, these funds can be used to pay prior year claims.

[The information follows:]

Fiscal year:

1992	\$12,965
1992	1,465,284
1991	1,523,515
1990	1,866,421
1989	6,506,462
1988	2,234,340
1987	904,203

Note: The table is updated to reflect unobligated funds as of 9/30/93. Funds listed for Fiscal Years 1987 and 1988 have been returned to the U.S. Treasury and are no longer available to pay claims.

FOOD PROGRAM ADMINISTRATION

NUTRITION EDUCATION

Mr. DURBIN. With Federal dollars available for domestic programs shrinking and the increased importance placed on health care, it is through nutrition education that we can teach the public ways to make their limited food resources stretch and instill proper nutrition habits. Many health problems in the country can be reduced or eliminated through proper nutrition. USDA spends millions on nutrition education in a number of different programs. In view of this, Joe and I have asked our investigative staff to look into the Departments overall nutrition education efforts. The preliminary report identified three findings. First, there is no national policy for nutrition education that incorporates all U.S. agencies. Second, USDA has not provided a strategy for prioritizing nutrition education funding or outcomes at an agency-wide level. And third, most of the nutrition education and information funds are distributed to and managed by State agencies and there is little effort made to oversee or evaluate State and local nutrition education activities to ensure they are accomplishing their objectives. How do you respond to these findings?

Mr. LUDWIG. Secretary Espy realizes the importance of coordinating nutrition education within the United States Department of Agriculture (USDA). Several activities are underway that will facilitate this coordination. First, in early June, 1994, a Nutrition Roundtable is being convened by Secretary Espy and Assistant Secretary Haas; this workshop will bring together nutrition leaders from around the country to discuss new visions for nutrition within USDA including future directions for nutrition education and nutrition communications.

A Nutrition Strategy Paper is being developed that will identify the broad nutrition policy themes that are priorities for USDA and the implications of these nutrition policies for current activities within USDA. This paper will allow the Department to articulate a cohesive strategy and how this strategy can guide modifications in our current activities.

USDA is working jointly with the Department of Health and Human Services, and the Agency for International Development to develop a United States Plan of Action for Nutrition that will build upon the nutrition objectives of the Healthy People 2000: National Health Promotion and Disease Prevention. Healthy People 2000 establishes 21 quantitative nutrition objectives relating to items such as: bringing child nutrition program meals into line with the Dietary Guidelines for Americans; reducing iron deficiency; reducing intake of fat, saturated fat, salt and sodium; increasing intake of fruits, fiber calcium; increasing breastfeeding; increasing consumer use of food labels; and increasing nutrition education in schools.

The Food and Nutrition Service (FNS) is developing a nutrition education strategic plan for all FNS programs that is scheduled to be finished in late 1994. We will forward this to you upon completion.

As with most programmatic administrative funds under current law, nutrition education funding is largely distributed to and managed by State agencies. FNS exercises its administrative and over-

sight role by requiring submission and approval of State plans for how the nutrition education funding will be used. Actual usage and nutrition education activities are reviewed during regular State and local management evaluations. In addition, we have increased research in nutrition education. A major study of nutrition education in the Special Supplemental Food Program for Women, Infants and Children (WIC) has collected formative information through focus groups with WIC participants and staff, and will begin collecting exploratory evaluation data in the summer of 1994. In Fiscal Year 1993, we initiated nutrition education demonstration projects in the Food Stamp Program at seven sites. These grants are: University of Hawaii/Extension Service/EFNEP—comparison and evaluation of 3 successively higher levels of educational interventions. This will include mailed brochures, a 10–15 minute video, and eight 2-hour lessons; University of North Carolina, Department of Public Health—tailored computer intervention for 300 (160 final) with a control in FSP office. The emphasis of this project is development and evaluation of a interactive computer program; University of California/Extension Service—EFNEP—evaluation of food/recipe videotapes now in use in FSP offices in 3 counties, with a control group. The emphasis of this proposal is evaluation of existing cooking show format videotapes; University of Arkansas Extension Service—development and evaluation of low literacy pamphlets sent monthly through the mail. Pamphlets designed to be read by parents to their children (944 participants); Rutgers Cooperative Extension—25–35 Seniors will participate in a four State program with counseling, demonstration and lectures covering education/shopping and cooking; Douglas-Cherokee Economic Authority, Inc.—a sample of 315 women, men, homeless and teen parents from age 16–44 will participate in 16 hours of education that will produce positive changes. Control group of 158 will be used as part of the evaluation process; and White Mountain Apache Tribe—600 cooking demonstrations and classes led by community members will be held to “saturate” the 7,000 FSP participants on the reservation. This year we will initiate innovation nutrition education demonstration projects in the WIC program and for cross-program nutrition education efforts by communities using funding from the research accounts for the Food Stamp Program, the WIC program and the Child Nutrition programs. For both sets of demonstration projects, local communities will compete for funding to implement the innovative nutrition education interventions, and an independent evaluation will be competitively awarded by FNS.

The combined effect of these actions should be a more integrated approach to nutrition education and ultimately improvement in the dietary patterns of Americans.

OFFICE CLOSURES

Mr. DURBIN. As part of the Departments reorganization efforts, the Food and Nutrition Service plans to close eight field offices. Please tell the Committee where each of these offices are located, how many employees will be affected by the closures, do you plan to carry out the work of these offices at other locations, and a list of the criteria used in selecting these offices for closure.

Mr. LUDWIG. As part of its reorganization package submitted to the Office of the Secretary, the Food and Nutrition Service (FNS) has proposed closing the following field locations: Mobile, Alabama; Tuscaloosa, Alabama; New Orleans, Louisiana; Knoxville, Tennessee; Memphis Tennessee; Corpus Christi, Texas; El Paso, Texas; San Antonio, Texas; Alexandria, Virginia; and Shawano, Wisconsin. Most of these satellite locations are one-person offices; a total of fourteen employees will be affected by the closings. They will be re-assigned to other field or regional locations. The work previously carried out in these locations will be transferred to other FNS field or regional locations. These locations were selected for closure because of the inefficiency of maintaining office facilities for one- and two-person offices; and the work performed in the offices can be performed by other, larger FNS facilities at the field and regional level.

A final decision has not yet been received from the Office of the Secretary regarding the closure of these offices, pending the approval of the overall USDA reorganization.

PUBLIC AFFAIRS OFFICE

Mr. DURBIN. The Food and Nutrition Service has an Office of Governmental Affairs and Public Information. What is the funding level of this office in both dollars and staff years? Why do you need an office separate from the Department-wide Offices of Public Affairs?

Mr. LUDWIG. The anticipated staff and salary funding levels for the Office of Governmental Affairs and Public Information OGAPI in Fiscal Year 1994 is 24.69 in staff years and \$1,455,712 in salary and benefits down from 26.89 staff years and \$1,544,268 in salary and benefits in Fiscal Year 1993.

FNS benefits from its own individual governmental/public affairs office—not to work independently from the Departmental offices, but to work with the Department. The FNS budget is 65% of the entire USDA budget while our governmental/public affairs office is one of the smallest in the Department. In line with Secretary Espy's streamlining of USDA, we have dropped from 26.89 staff years fiscal year 1993 to 24.69 staff years in Fiscal Year 1994.

As we move to shrink and streamline the Department's public affairs function, it is important that critical messages continue to reach our audience. Indeed, a lean and dedicated public affairs office at FNS is essential to carry out the Secretary's goal of elevating the importance of nutrition with the Department. We serve a unique clientele and provide services that include outreach initiatives to ensure our customers understand how best to access our programs. We are a nutrition based organization and our link to USDA, while vital, is unique. An individual governmental/public affairs office that centers on nutrition, access, and educational messages will best serve our mission.

FOOD STAMP NUTRITION EDUCATION

Mr. DURBIN. The notes state that you plan to continue working on the five year plan for nutrition education for the Food Stamp Program. Would you please describe this plan in further detail.

Mr. LUDWIG. The five year plan will be based on the results of the Food Stamp Program (FSP) Demonstration Grants, the FNS "Barriers to Good Nutrition" study, the status of projects to develop new nutrition education materials covered in the Memorandum of Understanding, as well as other projects to be developed which include: An information delivery plan for dissemination of FSP materials and messages, development of coupon book messages and information stuffers, development of educational objectives and strategies based on the needs of targeted segments of the FSP populations and other project ideas which are still being generated.

Mr. DURBIN. Provide a list and a brief description of all the Food Stamp Nutrition Education Demonstration Grants that are to be completed in fiscal year 1995.

Mr. LUDWIG. The emphasis of each grants is to demonstrate the effectiveness of different methods to provide nutrition information to different segments of Food Stamp Program (FSP) participants.

I will provide a list for the record.

[The information follows:]

The University of Hawaii/Extension Service/EFNEP is undertaking a comparison and evaluation of three successively higher levels of educational interventions. They will (1) mail nutrition brochures to all Hawaiian households participating in the FSP, and to sample FSP populations they will (2) conduct eight 2-hour lessons and (3) show a newly developed nutrition education video.

The University of North Carolina, Department of Public Health, is creating a tailored interactive computer program which will be evaluated with a FSP population of 300 individuals using the program at a FSP certification site.

The University of California/Extension/EFNEP will evaluate the effectiveness of food/recipe/cooking show format videotapes in three different counties.

The University of Arkansas/Extension Service will develop and evaluate the effectiveness of direct-mail low literacy pamphlets targeted to parents of young children.

The Rutgers Cooperative Extension (New Jersey) is targeting senior citizens who will participate in a four stage program with counseling, demonstration and lectures covering education/shopping and cooking. Evaluation will occur at each of the four stages of the project.

The Douglas-Cherokee Economic Authority, Inc. (Tennessee) will conduct and evaluate food/nutrition classes for women, men, homeless and teen parents from the age of 16-44.

The White Mountain Apache Tribe (Arizona) will conduct and evaluate the outcome of 600 cooking demonstration classes led by community members for the 7,000 FSP participants on the reservation.

QUALITY OF SCHOOL MEALS

Mr. DURBIN. One of your goals for the Child Nutrition Program is to undertake a major regulatory initiative to improve the quality of school meals consistent with the dietary guidelines. Please describe this initiative in further detail for the record.

Mr. LUDWIG. Prior to undertaking this regulatory initiative, the Department conducted a series of four public hearings and invited written comments on what the medical, scientific and education communities as well as the general public thought about school meals. Over 350 individuals testified at the hearings and over 2000 written comments were received. As expected, the medical and scientific communities provided a considerable amount of data attesting to the effects of poor nutrition on children's present and future health and well being.

Eating habits are firmly established by the age of 12, so the programs that deliver meals to children are a critical aspect in developing life-long dietary patterns. Low income, minority children in

particular suffer from childhood obesity and other diet-related problems with long term health consequences. The Department recognizes that we have a special responsibility to provide meals to children that make a positive contribution to their health and is committed to this goal.

The Department is planning a comprehensive, integrated approach to meet the challenge of providing nutritious, appealing school meals as soon as practically possible. After carefully reviewing the data, the Department is drafting a proposed rule which will address the broad range of issues involved with bringing school meals in compliance with the Dietary Guidelines for Americans. Since the rule is under development with final decisions pending on particular issues, we can not comment now on the specific provisions.

DIRECT CERTIFICATION—SCHOOL LUNCH PROGRAM

Mr. DURBIN. You plan to publish final regulations for direct certification of free meal eligibility in the school lunch program. Would you elaborate on what this means for the school lunch program and tell us when you expect to publish these regs.

Mr. LUDWIG. We have had positive feedback from State and local agencies that have implemented direct certification. Many are reporting an increase in school meal participation and a decrease in paperwork. The direct certification provision has been operational for several years. We hope to have a final regulation in place in late summer. In the meantime, States and localities are moving forward on the basis of program guidance.

WIC FULL FUNDING

Mr. DURBIN. Under the WIC program you plan to continue to coordinate with the public health care community at large to prepare WIC for sustained rapid growth toward eventual full funding. Tell us specifically what you are doing to prepare the community for this rapid growth as we move towards full funding.

Mr. LUDWIG. FNS has been involved in numerous activities to help the WIC community develop plans to address the challenges that program growth presents. Last Fall, the Assistant Secretary for Food and Consumer Services hosted a full-funding meeting for members of the WIC community. The National Association for WIC Directors, NAWD, held a follow-up meeting to discuss various strategies for working with the health care community to manage growth in local health departments, in which representatives from USDA and advocate groups participated. FNS is currently coordinating with the Center for Disease Control, CDC, to conduct patient flow analysis of local health departments. A dialogue has also been established between FNS and the Department of Health and Human Services, DHHS, to form a task group to develop a cost allocation guide to assist integrated local agencies in allocating costs among the programs that they operate. FNS is conducting a number of studies, including the WIC Dynamics Study, which will examine the issues involved in facilitating program expansion. FNS Regional Offices, in conjunction with their State agencies, have completed infrastructure surveys to identify current needs and establish systematic plans to accommodate rapid growth. In addition,

FNS issued a new instruction covering the purchase, renovation and repair of real property in order to assist State and local agencies in expanding their facilities. In summary, the Department is working on a wide variety of fronts to study, discuss, and guide States toward achieving full-funding goals. These efforts are intended not only to facilitate State full funding efforts, but also to continue to assist States in providing quality services more efficiently and cost-effectively.

DEPARTMENTAL INITIATIVES

Mr. DURBIN. You hope to obtain Departmental approvals for Electronic Data Interchange and Business Process Re-engineering initiatives. Please describe these initiatives in further detail.

Mr. LUDWIG. FNS has been actively pursuing the goal of electronic data interchange for our grantee reporting with several initiatives over the past few years. We initially developed the capability for regional office direct online data entry of reports and food coupon requisitions, and currently have been working to demonstrate the feasibility of direct data entry by our State agencies. This direct data entry would eliminate the need for them to submit hard copy reports to our regional offices and reduce the data entry burden on regional staff. While this initiative may prove viable for the short run, our long range goal is to allow State agencies to transmit report data directly from their computer systems to our automated program databases. This long range goal is the core of our Electronic Data Interchange initiative.

USDA objective for making the Electronic Benefit System available to all States by 1996, where cost-effective, requires, among other things, that FNS develop and implement a re-designed organizational and operational infrastructure, capable of handling this radically new environment. The Business Process Re-engineering initiative is designed to study the Agency's current food stamp activities, creating a baseline from which we can develop alternative functional processes and structures capable of handling and integrating the requirements for electronic benefit transfer of food stamp benefits into the overall structure of the Agency.

FOOD STAMP INVESTIGATIONS

Mr. DURBIN. You performed investigations on 4,644 stores operating in the food stamp program of which 1,387 stores or 30 percent disclosed violations serious enough to warrant disqualification or other sanction action. How many of these stores were actually disqualified?

Mr. LUDWIG. During Fiscal Year 1993, 842 stores were disqualified from the Food Stamp Program. In addition, civil money penalties were imposed against 210 firms in lieu of disqualification. Action has not been completed, however, on all of the Fiscal Year 1993 cases. A significant number are still awaiting a final outcome; some are in administrative review and others are in judicial review.

KENTUCKY AND IOWA DEMONSTRATIONS

Mr. DURBIN. What is the status of two statewide demonstration projects that were conducted in Kentucky and Iowa to test eligibility changes in the Child and Adult Care Food Program?

Mr. LUDWIG. Currently, there are 165 sponsors, 157 in Kentucky and 8 in Iowa, of 227 centers, 219 and 8, respectively, participating in the Kentucky and Iowa Demonstration Projects. Total monthly enrollment for these centers is 14,181 children. The total average monthly reimbursement is \$320,000. Centers participating in the demonstration received approximately \$3.6 million in fiscal year 1993 and we expect to provide about \$3.7 million in discretionary funds in fiscal year 1994.

NEW SCHOOL LUNCH COMMODITY

Mr. DURBIN. During fiscal year 1993, a new commodity, ribbed-shaped patties, were offered to school districts. What are ribbed-shaped patties?

Mr. LUDWIG. This commodity is a frozen, fully cooked, pork patty which is ribbed-shaped in appearance and is lightly seasoned with barbecue mix. A serving suggestion for the product is on a bun or Kaiser roll with barbecue sauce. The product has a maximum fat content level of 21 percent and is being offered under the State Option Contract, SOC Program. Those States ordering the product through the SOC Program this year included Indiana, New Jersey, West Virginia and Virginia.

The introduction of this and other products is intended to assist schools to use USDA commodities in the preparation of meals which are both healthful and appealing to mean program participants.

COMPETITIVE FOODS

Mr. DURBIN. The Nutrition and Technical Services staff prepared a final rule for competitive foods to replace USRDA's with RDI's. Would you describe this initiative in further detail including a summary of the difference between a USRDA and RDI.

Mr. LUDWIG. This rule change is to bring the competitive foods rule in line with the Food and Drug Administration's (FDAs) recent regulations involving nutrition labeling. FDA's regulations discontinue the use of the term "U.S. Recommended Daily Allowances (U.S.RDA)" as the food labeling reference value and implement the use of the term "Reference Daily Intake" or "RDI." This change is one of designation only and the actual reference values are not being modified.

Mr. DURBIN. Does this new rule have any affect on the foods contained in the WIC food packages?

Mr. LUDWIG. The new rule will not have any effect on the foods contained in State agencies to assist them in interpreting the new labeling for WIC foods. Where WIC regulations set forth standards for foods in terms of Recommended Daily Allowances, RDA's, such as WIC cereals, some interpretive guidance will be issued to allow WIC State agencies to determine which foods are allowable for WIC under the new RDI labeling system. USDA has agreed to conduct a workshop at the upcoming National Association of WIC Di-

rectors meeting in Chicago in early April on the conversion process. We anticipate no problems with the changeover to RDI's in the WIC Program. Foods that were eligible for WIC under the RDA labeling system will continue to be allowable for use in WIC under the RDI labeling system.

NUTRITION EDUCATION AND TRAINING STRATEGIC PLAN

Mr. DURBIN. A national conference was held in fiscal year 1993 to introduce the Nutrition Education and Training Strategic Plan for Nutrition Education. Please describe this plan in further detail including the cost of implementation.

Mr. LUGWIG. The Strategic Plan for Nutrition Education was developed in response to recommendations in the 1990 report, Nutrition Education Needs of Children which was prepared in fulfillment of the Congressional mandate under Public Law 101-147. A key recommendation offered in the report was the need to develop a national framework for the Nutrition Education and Training Program (NET). Development of the Plan included input from over 100 individuals from State and Regional NET Offices and major allied health and nutrition agencies and organizations. The plan begins with a philosophy statement that describes the scope and benefits of the NET Program. A strategic direction was produced which depicts what NET would want nutrition education to look like in the year 2000. The last component of the plan is ten national goals that are categorized as leadership goals, nutritious meal service goals and nutrition education and training goals. Many of these goals closely parallel goals in Healthy Children 2000 and America 2000, An Education Strategy, thus underscoring the national emphasis and partnership links.

NET is the nutrition education component of USDA's food assistance programs for children: National School Lunch, School Breakfast, Summer Food Service and Child and Adult Care Food Programs. The national strategic plan goals address delivery of nutrition services to all of these programs and their target audiences of children, teachers, parents, caregivers and food service personnel. The NET Strategic Plan provides a strong foundation for State NET Coordinators to build an ongoing, successful nutrition education program in every State. The leadership goals in the Plan challenge USDA Headquarters to provide technical assistance to States in the form of a Needs Assessment Guide and Evaluation Guidelines. These tools will assist State NET Coordinators in their efforts to strengthen programs and provide greater program accountability.

The Department's budget request \$10.3 million for the NET program in Fiscal Year 1995. We believe that this amount, in addition to the \$20.5 million requested to implement the Dietary Guidelines in schools, is adequate to implement the plan. In addition, the cost of implementation of the national goals that are the responsibility of USDA Headquarters is estimated at approximately \$100,000 per year. This amount is included in our Food Program Administration account in our request.

Mr. DURBIN. The Nutrition and Technical Services staff have signed a Memorandum of Understanding with the Food Stamp Program to assume the responsibility for developing a nutrition edu-

cation plan for the program over the next three years. Describe this initiative in further detail for the record.

Mr. LUDWIG. The Nutrition and Technical Services Division will develop a series of nutrition education materials to replace the outdated Food Stamp Program materials previously created to meet the legislative mandate requiring nutrition education posters and pamphlets. The new Food Stamp Program booklet "Building Better Eating Habits," which is coordinated with a companion poster, is currently in the final technical clearance phase by both the Department of Health and Human Services and USDA. Other materials now in development will cover parenting tips on feeding children, food shopping, food preparation and recipes.

NTSD staff also oversee the Fiscal Year 1993 FSP Demonstration Nutrition Education Grants which are intended to demonstrate and evaluate the effectiveness of different methods of providing nutrition information to different segments of the FSP participant population.

EBT

Mr. DURBIN. An evaluation of the EBT systems in New Mexico and Ramsey County, Minnesota were published in fiscal year 1993. Briefly describe the results of these evaluations and submit a copy of each for the record.

Mr. LUDWIG. The report entitled "The Impacts of the State-Initiated EBT Demonstrations on the Food Stamp Program" provides the results of the evaluations in New Mexico and Ramsey County, Minnesota. The main purpose of the State-initiated demonstrations was to determine if it is possible for State agencies and their Electronic Benefit Transfer vendors to design and operate EBT systems that are secure and acceptable for participants and retailers, yet have costs approaching those associated with current coupon-based issuance systems. A copy of this report and a report entitled "The State-Initiated EBT Demonstrations: Their Design, Development and Implementation," which provides an account of the processes by which the sites implemented their EBT systems, will be submitted for the record. I will also submit a brief description of the findings of the report.

[The information follows:]

EBT administrative operating costs are lower than coupon issuance costs in each site. The operating cost of issuing food stamp benefits electronically under the EBT system is \$3.07 per case month in New Mexico compared to the paper coupon issuance cost of \$4.04. In Ramsey County, the EBT cost was \$4.38 per case month while the paper coupon issuance cost was \$4.53. (These costs do not include the cost to design, develop and implement the EBT systems.)

The estimated level of benefit loss and diversion in the Food Stamp Program is reduced under both EBT systems. In New Mexico, estimated benefit loss and diversion rates declined from \$4.37 per case month under coupons to \$1.09 with EBT. This was a 75 percent reduction. These rates decreased from \$5.29 to \$1.01 per case month in Ramsey County, an 81 percent reduction.

Both EBT systems reduce retailers' costs to participate in the Food Stamp Program, and retailers in both sites prefer EBT. EBT reduces participation costs for retailers in New Mexico by an average of \$3.98 for every \$1,000 of food stamp sales and by \$9.09 in Ramsey County. Retailers' in New Mexico prefer EBT to coupons by a margin of 7 to 1. Retailers in Ramsey County also prefer EBT, but by a smaller margin, 1.4 to 1.

Food stamp recipients' participation costs decrease under EBT and they strongly prefer the EBT systems to coupons. Average recipient participation costs in New

Mexico declined from \$3.89 per month with coupons to \$1.44 with EST. Ramsey County recipients' costs decreased from an average of \$3.59 with coupons to \$1.95 under EBT. Recipients prefer EBT to coupons by a margin of 29 to 1 in New Mexico and 4 to 1 in Ramsey County.

Financial institutions strongly prefer EBT and their costs were reduced under the EBT systems. The net costs of participation for local banks fell by \$3.17 and \$5.48 per \$1,000 of benefits redeemed in New Mexico and Ramsey County, respectively. Concentrator banks which transfer EBT credits to the retailers' depository bank via the Federal Reserve's automated clearinghouse charge fees that offset their costs. The Federal Reserve Banks incurred no net costs under either system because their fees are designed to cover their costs. All bank representatives interviewed prefer the EBT systems.

Despite the positive achievement of the New Mexico and Ramsey County EBT demonstrations, it cannot be assumed that EBT systems in other locations will be cost-competitive as well. The cost-competitiveness of other EBT systems will depend on: (1) the efficiency of client training and card issuance; (2) the fees and other charges paid to the system operator; (3) the extent to which network costs are shared with retailers and third-party networks; (4) EBT project management and support costs; and (5) the cost of the coupon system being replaced.

[CLERK'S NOTE.—The full report is too lengthy for reprint. A copy is retained in Committee files.]

MULTI-YEAR GRANTS

Mr. DURBIN. During fiscal year 1993, FNS awarded five capacity-building grants to 1890 Land Grant Universities. Describe these grants for the record including the cost and location of each grant.

Mr. LUDWIG. FNS did not award any capacity-building grants to 1890 Land Grant Universities in Fiscal Year 1993. However, FNS did award four multi-year grants to 1890 Land Grant Universities in Fiscal Year 1992 and one multi-year grant in Fiscal Year 1991 which are still continuing. I will provide information which describes the purpose, cost, and location of those grants for the record.

[The information follows:]

1. "Strengthening and Expanding Academics in Food and Nutrition for the 21st Century". Tuskegee University, Tuskegee, Alabama. Total cost: \$157,500. The project augments the existing food and nutritional science M.S. program by providing an option in community nutrition and adding a faculty member to the existing dietetics graduate program. Through a variety of incentives, this expanded program is designed to increase recruitment and retention by attracting high-achiever students, who may otherwise attend larger, better financed colleges and universities.
2. "Enhancing the Dietetics Program at the University of Maryland, Eastern Shore". University of Maryland, Eastern Shore, Princess Anne, Maryland. Total cost: \$169,548. This project will strengthen teaching capacity and student recruitment and retention in nutrition and dietetics programs at the institution. Innovative marketing strategies and experiential learning will be utilized. Curriculum will be revised to include a community nutrition component; partnerships will be developed among Dietetic Program faculty of the institution, community nutrition professionals, USDA agencies, and other universities that provide nutritional care/services.
3. "Student Education, Enhancement and Development (SEED)". Lincoln University, Jefferson City, Missouri. Total costs: \$188,532. This project will enhance existing recruitment and retention programs designed to attract minority students who are interested in agriculture, natural resources, and home economics. Project SEED builds on previously successful summer programs of the institution and concentrates on providing high school students with an experience in research. Research methodology activities, career exploration activities, and ethics in science activities comprise the summer phase of the program.
4. "Recruitment and Retention of Ethnic Minorities in Nutrition and Dietetics Program". Langston University, Langston, Oklahoma. Total cost: \$202,401. Project increases minority student recruitment, enrollment and retention in the Nutrition and Dietetics Program by implementing aggressive marketing strategies targeted to culturally diverse high school population in the State of Oklahoma. Through sum-

mer workshops, high school students, secondary school teachers, counselors, and community leaders will become aware of the various career opportunities in food nutrition and dietetics. Collaborative efforts with Federal and state agencies will enhance students learning and career options by participating in the summer practicum.

5. "Strategies in Increase Minority Representation in Nutrition and Dietetics". University of Arkansas—Pine Bluff, Arkansas. Total cost: \$202,485. This project will provide a comprehensive marketing program to increase the visibility of the nutrition and dietetics professions, thereby positively affecting the available supply of minority professionals in the food and agricultural labor force. Tutoring, counseling, advising and mentoring will be provided high school and undergraduate students, along with the provision of apprenticeships and internships to enhance career awareness and leadership development.

Mr. DURBIN. Were any grants awarded in fiscal year 1994?

Mr. LUDWIG. No grants have been awarded this year.

WORLD FOOD DISTRIBUTION TRAINING CENTER OF EXCELLENCE

Mr. DURBIN. Also during fiscal year 1993, the Department provided \$30,000 in start-up funds to the World Food Distribution Training Center of Excellence of Prairie View University. Tell the Committee more about this Center. What is its mission? Will the Department continue to provide funding in fiscal years 1994 and 1995? If so, how much. Are Federal staff operating the Center?

Mr. LUDWIG. The 1890 Initiative/Centers of Excellence idea was conceived by the Department as a means of participating with the 1890 historically Black Land-Grant Universities' HBLGU, on programs of significant value to the Department in the fields of agriculture, agri-business, and the food services; and to train minorities for work in these fields, thus creating a resource from which USDA agencies and the private sector can hire diverse employees.

The goal of World Fund Distribution Training Center For Excellence, WFDTTC, is to create the opportunity for Prairie View A&M University and collaborating universities Texas A&M University, Texas A&M University Kingsville, and Texas A&M International to undertake World Food Distribution Training with a special emphasis to recruit minorities, African Americans, Hispanics, and American Indians, and to enable graduates to effectively compete for management careers in domestic and international food and fiber transportation, distribution, and logistics. The shortage of minorities trained in this field has been confirmed by the number of minorities working in the field.

FNS is one of five USDA agencies supporting the Center, the others are Agricultural Marketing Service, the lead agency, Economic Research Service, Foreign Agricultural Service, and the Agricultural Stabilization and Conservation Service. In addition, private organizations, such as the National American Wholesale Grocers Association are actively supporting the project. The Department's 1995 Budget proposal includes funding for the Center of Excellence by AMS. The USDA agencies provided interim funding in fiscal year 1993 and will continue this developmental funding in fiscal year 1994. For these two fiscal years the FNS support is \$28,500 and \$25,000 respectively. FNS expects to continue support of the WFDTTC through internships, scholarships, IPA assignments and technical support whenever these can be appropriately provided.

Involvement in the project will provide FNS with a pool of qualified minorities to fill positions in our Food Distribution Program and the State agencies administering our programs. In addition, the Center will provide FNS the opportunity to network with the 1890 HBCUs, the collaborating universities, State agencies, and private sector firms and organizations. Building a support group from these contacts will enhance our efforts to meet the need of our program recipients.

PROGRAM INFORMATION

Mr. DURBIN. For each of the 15 programs in the Food and Nutrition Service, please provide a table that includes the following information: the age eligibility of participants, the income eligibility of participants, what percent of poverty this income level is, the total number of people served, and what percent of the total eligible is being served.

Mr. LUDWIG. I will provide the information for the record.
[The information follows:]

Attachment for DUR 201:

Information on the Fifteen Domestic Nutrition Assistance Programs

Program	Age Eligibility Requirements	FY 1994 Income Eligibility Requirements	% of Poverty of Income Eligibility Requirements	# of Individuals Served	Individual Participation Rate
Food Stamp Program	none	\$1,555 max. monthly gross income and \$1,196 max. monthly net income for household size 4 [households w/elderly or disabled must meet net test only]	130% for gross monthly income; 100% for net monthly income	27 million a month average in FY 1993	60% in Jan. 1989
Nutrition Assistance Program in Puerto Rico	none	\$8,000 max. annual gross income for household size of four	56%	1.4 million in FY 1993	unknown

Program	Age Eligibility Requirements	FY 1994 Income Eligibility Requirements	% of Poverty of Income Eligibility Requirements	# of Individuals Served	Individual Participation Rate
Special Supplemental Food Program for Women, Infants, and Children (WIC)	Pregnant, postpartum and breast-feeding women, children up to age 5	\$2,213 per month based on household size of four	185%	5.9 million average per month in FY93	60% in FY92
WIC Farmers Market Nutrition Program	Pregnant, postpartum and breast-feeding women, children up to age 5	\$2,213 per month based on household size of four	185%	not available	not available
Commodity Supplemental Food Program	children up to age 6, elderly 60 or older, pregnant, postpartum or breast-feeding women	elderly - \$1,604 per month max.; for all others, they are eligible if they are eligible for other Federal, State or local programs for low-income persons	elderly - 130%; all others State determines	36,000 women; 22,000 infants; 170,000 children; 142,000 elderly	
National School Lunch Program	school-age children	\$2,213 max. for reduced price meals and \$1,555 per month for free based on monthly gross income for a family of four	131 to 185% of poverty to receive reduced price meals; 130% or below to receive free meals	25.5 million children per day	On any given day 79% of free eligibles, 71% of reduced price eligibles and 45% of paid eligibles participate.

Program	Age Eligibility Requirements	FY 1994 Income Eligibility Requirements	% of Poverty of Income Eligibility Requirements	# of Individuals Served	Individual Participation Rate
School Breakfast Program	school-age children	\$2,213 per month max. for reduced price meals and \$1,555 per month for free based on monthly gross income for a family of four	131 to 185% of poverty to receive reduced price meals; 130% or below to receive free meals	5.4 million children per day.	On any given day 44% of free eligibles, 15% of reduced price eligibles and 5% of paid eligibles participate.
Child and Adult Care Food Program	up to 12, 15 for migrants and any age for handicapped and adults in day care centers	\$2,213 max. for reduced price meals and \$1,555 per month for free based on monthly gross income for a family of four	131 to 185% of poverty to receive reduced price meals; 130% or below to receive free meals	1.95 million per day on average	not known
Summer Food Service Program	children up to age 18	\$1,604 per month max.	130% or less	2.1 million	not available
Special Milk Program	school-age children or children under 19 years in child care institutions or under 21 in residential child care institutions	\$1,555 per month for free milk based on monthly gross income for a family of four	130% or less	not available	not available

Program	Age Eligibility Requirements	FY 1994 Income Eligibility Requirements	% of Poverty of Income Eligibility Requirements	# of Individuals Served	Individual Participation Rate
Nutrition Program for the Elderly	persons 60 or over and their spouses	none	none	244 million meals	unknown
Food Distribution Program on Indian Reservations	none	\$1,327 per month max. for a family of 4	130%	112,000	not available
Emergency Food Assistance Program	none	State determine - \$2,282 per month max.	State criteria must be between 125% and 185%	unknown	not available
Commodity Distribution to Food Banks and Soup Kitchens	none	If they serve TEFAP foods - States determine with a max. of \$2,282 per month; all others determine their own criteria	If they serve TEFAP foods - State criteria must be between 125% and 185%; all others determine their own	not available	not available
Nutrition Education and Training Program	not available	not available	not available	not available	not available

HISTORY OF FOOD STAMPS

Mr. DURBIN. A number of years ago, a report on the history of the Food Stamp Program was included for the record. Would you please update this report and include a copy for the record.

Mr. LUDWIG. Unfortunately, that report is no longer compiled. However, I will submit the most recent Food Program Facts which contains similar information for the record.

[The information follows:]

Food Program Facts

Food and Nutrition Service
U.S. Department of Agriculture

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THE FOOD STAMP PROGRAM

May 1993

1. What is the Food Stamp Program?

Food coupons, or stamps, are used to supplement the food buying power of eligible low-income households. The program is administered nationally by the U.S. Department of Agriculture's Food and Nutrition Service (FNS) and locally by the State welfare agencies. The purpose of the program is to improve the levels of nutrition among low-income households and to strengthen the agricultural economy through normal channels of trade.

2. Who is eligible to receive food stamps?

The program provides monthly benefits to low-income households to help them purchase a more nutritious diet. To qualify for the program, households must meet eligibility criteria and provide proof of their statements about household circumstances. U.S. citizens and aliens who by law are considered admitted for permanent residency may qualify.

To participate in the Food Stamp Program:

- Most able-bodied adult applicants must meet certain work requirements.
- All households may have \$2,000 in countable resources, such as a bank account. Households may have \$3,000 if at least one person is age 60 or older. Certain resources are not counted, such as a home and lot. Special procedures are used to determine the resource value of licensed vehicles.
- All household members must provide a Social Security number or apply for one;
- The gross monthly income of most households must be at or below 130 percent of the Federal poverty guidelines (\$1,512 a month for a family of four in Fiscal Year 1993), and their net income must be at or below 100 percent of the Federal poverty guidelines for their household size (\$1,163 a month for a family of four in FY 1993). Households with an elderly or disabled member are subject only to the net income test. Gross income includes all cash payments to the household with the exception of a few specific types identified by law or regulation.

Federal poverty guidelines are established by the Office of Management and Budget, and are updated annually by the Department of Health and Human Services.

Food Program Facts / The Food Stamp Program

The maximum gross income eligibility standards effective October 1, 1992 to September 30, 1993 are:

GROSS MONTHLY INCOME ELIGIBILITY STANDARDS (130% of Poverty Line)

HOUSEHOLD SIZE	48 STATES (1)	ALASKA	HAWAII
1	738	921	849
2	996	1,244	1,146
3	1,254	1,567	1,442
4	1,512	1,890	1,739
5	1,770	2,213	2,036
6	2,027	2,535	2,333
7	2,285	2,858	2,630
8	2,543	3,181	2,927
Each additional member	+258	+323	+297

1) Includes District of Columbia, Guam and Virgin Islands

3. How is net income determined?

Net monthly income is used to determine a household's benefit level. Food stamp net income is figured by adding all of a household's gross income, except that excluded by law, and then subtracting certain deductions:

- An earned-income deduction for households with working members equal to 20 percent of the combined earnings of household members;
- A standard deduction adjusted annually to reflect changes in the cost of living. The standard deduction for most households in the 48 contiguous states and the District of Columbia is \$127 in Fiscal Year 1993;
- A dependent care deduction (not to exceed \$160 per month for each dependent) for the expenses involved in caring for children or other dependents while household members work or seek employment;
- An excess shelter expense deduction for those shelter costs (such as rent, mortgage payments, utility bills, property taxes, and insurance) that exceed 50 percent of the household's remaining income after all other deductions are taken. The shelter deduction cap is adjusted annually, but in Fiscal Year 1993 most households have a shelter deduction cap of \$200 a month. Households with an elderly (age 60 or older) or disabled member are exempted from this limit—they may subtract the full value of all shelter costs greater than 50 percent of their adjusted income.
- A special medical deduction is available to households with an elderly or disabled member. These households may deduct all medical costs exceeding \$35 incurred by the elderly or disabled person. Medical expenses reimbursed by insurance or government programs are not deductible.

Food Program Facts / The Food Stamp Program

The net monthly income eligibility standards effective October 1, 1992 to September 30, 1993 are:

NET MONTHLY INCOME ELIGIBILITY STANDARDS 100% of Poverty line)

HOUSEHOLD SIZE	48 STATES (1)	ALASKA	HAWAII
1	568	709	653
2	766	957	881
3	965	1,205	1,110
4	1,163	1,454	1,338
5	1,361	1,702	1,566
6	1,560	1,950	1,795
7	1,758	2,199	2,023
8	1,956	2,447	2,251
Each additional member	+199	+249	+229

1) Includes District of Columbia, Guam and Virgin Islands

4. How is each household's food stamp allotment determined?

Households are issued an allotment of food stamps. The maximum household allotment is based on the Thrifty Food Plan for a family of four persons with a man and woman ages 20-50 and two children ages 6-8 and 9-11. The allotment level is then adjusted for household size and economies of scale, increased by 3 percent, then rounded down. In order to obtain an individual household's allotment, 30 percent of the individual household's net income is subtracted from the maximum allotment for that household's size. The Thrifty Food Plan is a low-cost model diet plan based on the Recommended Dietary Allowances and food choices of low-income households.

The current maximum allotment levels in effect from October 1, 1992 to September 30, 1993 are:

MAXIMUM ALLOTMENT LEVELS

HOUSEHOLD SIZE	ALLOTMENT LEVEL
1	\$111
2	203
3	292
4	370
5	440
6	528
7	584
8	667
Each additional member	+83

There are separate, higher allotment levels for urban Alaska, rural Alaska, Hawaii, Guam, and the Virgin Islands. These separate allotment levels reflect higher food prices in those areas. Households with no countable income receive the maximum allotment. For households that have countable income, benefits are reduced by 30 cents for each dollar of net income.

Food Program Facts / The Food Stamp Program

5. On average, how much help does the Food Stamp Program provide?

The average monthly benefit per person was \$68.57 for Fiscal Year 1992.

6. What foods are eligible for purchase with Food Stamps?

Households can use food stamps to buy any food or food product for human consumption, and seeds and plants for use in home gardens to produce food.

Households CANNOT use food stamps to buy:

- alcoholic beverages and tobacco;
- hot foods ready to eat and food intended to be heated in the store;
- lunch counter items or foods to be eaten in the store;
- vitamins or medicines;
- pet foods;
- any non-food items (except seeds and plants).

Restaurants can be authorized to accept food stamps in exchange for low-cost meals from qualified homeless, elderly or disabled people. Food stamps cannot be exchanged for cash.

7. What are some of the major characteristics of Food Stamp households?

Based on a summer 1991 characteristics study:

- 52.2 percent of all participants are children.
- 7.1 percent of all participants are elderly.
- The average household size is 2.6 persons.
- The average gross monthly income per food stamp household is \$472, or the annual equivalent of \$5,664. The average net income is \$261 a month – \$3,132 a year.
- Average countable assets per household are \$74, but for households with elderly members the average is \$184.
- About 4.6 percent of participants are employed full time (11.3 percent of non-elderly adult participants); 19.8 percent of households have earned income.
- 29 percent of household heads are registered for work through the Food Stamp Program or through the work requirements of other programs such as Aid to Families with Dependent Children and Unemployment Compensation Program. Most others are disabled or responsible for the care of a child or incapacitated person.

Food Program Facts / The Food Stamp Program

8. Who is required to work?

Physically and mentally fit food stamp recipients 16 to 59 years of age—with certain exceptions—are required to register for work, participate in an employment and training program if assigned, and accept suitable employment if it is offered.

Exceptions to the work requirement are:

- A person age 16 or 17 who is not a head of a household or who is attending school, or enrolled in an employment training program;
- Those who are subject to and complying with the work requirements of Title IV of the Social Security Act;
- A parent or other household member responsible for the care of a child under 6 or someone who is incapacitated;
- A person receiving unemployment compensation or an applicant for unemployment compensation who is complying with the local employment office's work requirements;
- A regular participant in a drug addiction or alcoholic treatment and rehabilitation program;
- Those employed at least 30 hours per week or receiving weekly wages equal to the Federal minimum wage multiplied by 30 hours;
- Students in compliance with food stamp eligibility rules that apply to them.

Because of these exceptions, only about 8 percent of all food stamp recipients are registered for work.

9. Does USDA have employment and training programs?

Legislation passed in 1985 required States to implement an employment and training (E&T) program for food stamp work registrants and selected volunteers. The program aims to involve these recipients in work-related activities that will lead to paid employment and a decreased dependency on assistance programs. USDA provides financial support to each State to operate its E&T program. Slightly more than 1.5 million food stamp recipients participated in E&T in FY 1992.

10. What prevents food stamps from being issued to people who don't qualify?

State qualification workers evaluate each application carefully to determine eligibility and to ensure that the proper level of benefits is authorized. A quality control (QC) system monitors the accuracy of the food stamp eligibility and benefit determinations made by the States. States that fail to meet a standard of accuracy in issuing their food stamp benefits are liable for the funds they issue in error. People who receive food stamp benefits in error must repay any benefits for which they did not qualify.

11. How much has the program cost over the years?

The Food Stamp Program began as a pilot project in 1961 and was authorized as a permanent program to operate at State option in 1964. Expansion of the program occurred most dramatically after 1974 when Congress required all States to offer food stamps to low-income households. Program growth has continued since then. Participation peaks in periods of high unemployment, inflation and recession.

Food Program Facts / The Food Stamp Program

FOOD STAMP PROGRAM GROWTH ¹⁾

Fiscal Year	Persons* (millions)	Coupon value (billions)	Monthly average per person	Total federal cost (billions)
1971	9.4	\$1.5	\$ 13.55	\$ 1.6
1972	11.1	1.8	13.48	1.9
1973	12.2	2.1	14.60	2.2
1974	12.9	2.1	17.61	2.8
1975	17.1	4.4	21.40	4.6
1976	18.5	5.3	23.93	5.7
1977	17.1	5.1	24.71	5.5
1978	16.0	5.1	26.77	5.5
1979	17.7	6.5	30.59	6.9
1980	21.1	8.7	34.47	9.2
1981	22.4	10.6	39.49	11.1
1982	21.7	10.2	39.17	10.8
1983	21.6	11.2	42.98	11.8
1984	20.9	10.7	42.74	11.6
1985	19.9	10.8	44.99	11.7
1986	19.4	10.6	45.49	11.6
1987	19.1	10.5	45.78	11.6
1988	18.6	11.1	49.83	12.3
1989	18.8	11.7	51.85	12.9
1990	20.1	14.2	58.93	15.5
1991	22.6	17.3	63.83	18.8
1992	25.4	20.9	68.57	22.5
1993	26.6	9.1	68.49	9.5 (FY 1993 figures as of February)

1) Excludes Puerto Rico

*Average monthly participation

FOOD STAMP TIMELINE

Today's Food Stamp Program stems from the food assistance programs of the Great Depression—a time when farmers were burdened with foods they could not sell, while thousands stood in bread lines, waiting for something to eat. To help both farmers and consumers, the Federal government began distributing surplus foods to the Nation's hungry citizens.

The 1930's — By the late 1930's, the Department was using an alternative approach known as the Food Stamp Plan. Under the plan, families exchanged money for stamps of equal value to purchase regular food items. They also received additional stamps to buy designated surplus foods at retail stores. First used in Rochester, NY, the Food Stamp Plan later expanded to 1,471 counties and 88 cities.

1943 — The Food Stamp Plan ended in 1943 as World War II reduced food surpluses and unemployment. At its peak, however, the program served well over 3 million people a month.

Food Program Facts / The Food Stamp Program

1950 -- Because of the depressed economy in the mid 1950's some areas decided to re-establish systems for distributing surplus foods to needy people, and interest in the Food Stamp Program revived.

1961 -- In 1961, USDA was directed by the President to establish a pilot Food Stamp Program. By August 1964, the pilot program was operating in 43 project areas and reaching over 350,000 people.

1964 -- The Food Stamp Act of 1964 established the Food Stamp Program as a permanent program and authorized expansion to States wishing to take part. During the following years, USDA undertook a campaign to bring some form of food assistance--direct food distribution or food stamps--to every county in the country.

At the same time, public awareness and concern about the food problems of the poor focused national attention on the food assistance programs. This concern culminated in a national commitment to end poverty-related hunger and malnutrition.

1969 -- In 1969, Congress greatly increased appropriations available to the Food Stamp Program. USDA continued to encourage program expansion, and by the end of 1970, only 39 areas were without either food distribution or food stamps.

1971 -- In 1971, Congress established uniform national standards of eligibility and required all States to inform low-income people about the availability of food stamps.

1974 -- In 1974, the Food Stamp Program finally went nationwide. P.L. 93-86 (August 10, 1973) mandated statewide operation of the FSP if any area of the State operated the program. Such States were to implement statewide operation by July 1, 1974.

1977 -- The Food Stamp Act of 1977 eliminated the purchase requirement, lowered net income limits to the poverty line, replaced most itemized deductions with a standard deduction, and tightened program requirements in a number of areas pertaining to students, aliens and fraudulent households.

1985 -- The Food Security Act enacted a number of Food Stamp Program provisions, including making households in which all members receive AFDC, SSI, or other Social Security disability payments categorically eligible through 1989; improved services to farm self-employed households; uncoupled the child care and shelter deductions and raised the deduction limits; raised household asset limits; improved services to the homeless; and required an Employment and Training Program by April 1, 1987.

1986 -- Services to the homeless were improved through provisions of the Homeless Eligibility Clarification Act (October 27, 1986). These services were further refined through the Stewart B. McKinney Homeless Assistance Act in July of the following year.

1988 -- The Hunger Prevention Act of 1988 (P.L. 100-435, September 19, 1988) raised maximum program allotments for FY 1989 and subsequent years; continued the categorical eligibility provisions of the Food Security Act of 1985; improved services to program applicants; refined the program's Employment and Training Program and quality control system; and permitted Federal funding of State outreach activities, among other program refinements.

1990--The Mickey Leland Memorial Domestic Hunger Relief Act (P.L.101-624, November 28, 1990) reauthorized the program through 1995; imposed new and increased penalties for fraud and trafficking; provided for the use of electronic benefit transfer as a means of issuing benefits;

Food Program Facts

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The Nutrition Assistance Programs in Puerto Rico and the Northern Marianas

May 1993

1. What is the Nutrition Assistance Program in Puerto Rico?

The program provides block grant funds to Puerto Rico. These funds are then used by the Commonwealth to give cash to the needy to buy food. The grant can also be used to fund up to 50 percent of administrative expenses, or to fund special projects related to food production and distribution.

As required by the Omnibus Budget Reconciliation Act of 1981, the Nutrition Assistance Program replaced the Food Stamp Program in Puerto Rico in 1982.

2. How much money is given to Puerto Rico and how do they use it?

President Clinton's 1994 budget request includes \$1.091 billion for Puerto Rico. Congress appropriated \$1.051 billion in FY 1993. The program served an average of 1.48 million people per month in 1992. Total benefit costs were estimated at \$971 million, or about \$54.76 per person per month.

3. What is the history of the Nutrition Assistance Program in Puerto Rico?

Prior to 1974 USDA distributed agricultural commodities directly to low-income residents of Puerto Rico through the Food Distribution Program.

From 1974 to 1982 Puerto Rico participated in the Food Stamp Program. The program there operated similarly to the program on the mainland with a few exceptions. The shelter and dependent care deductions for Puerto Rico, for example, were lower to account for the differences in the cost of living. USDA also used a special version of the Thrifty Food Plan tailored to food preferences and costs in Puerto Rico. The cost of this plan was usually less than the cost of the plan used in the States.

By 1981, the last year that the Food Stamp Program operated in Puerto Rico, 1.8 million people--56 percent of the Commonwealth's population--participated in the program. Food stamp benefits represented 8 to 10 percent of Puerto Rico's income. Eight percent of the total federal program expenditures for food stamps were spent in the Commonwealth--more than in any of the fifty States.

The legislation to create the Nutrition Assistance Program developed out of recognition that Puerto Rico's food stamp program had grown rapidly and that alternative approaches might better serve the Commonwealth. Based on 1980 data, projections for Fiscal Year 1982 estimated that food stamp participation in Puerto Rico would account for 10 percent of total program expenditures and would exceed \$1 billion. Puerto Rico had one of the highest food stamp error rates in the program: 14 percent of all benefits were paid out in error in the first half of Fiscal Year 1981, and the illegal sale of food stamps for cash appeared to be a significant and widespread problem.

Food Program Facts /Puerto Rico and Northern Marianas

Congress was concerned about how the Food Stamp Program had changed the economy of Puerto Rico. Congressional committees heard testimony that economic dependency on food stamps was increasing, while fewer people were working in agriculture, using less land for farming, and producing fewer crops.

Since Puerto Rico has been under the Nutrition Assistance Program, it has used some of its grant funds for special projects to strengthen agricultural production, including an initiative to eradicate cattle ticks.

4. What is the Nutrition Assistance Program in the Northern Mariana Islands?

The program provides annually \$3.7 million in block grant funds to the Commonwealth of the Northern Mariana Islands for food assistance to the needy. These monies consist in part of unexpended funds from prior years. The \$3.7 million grant has been unchanged since the Nutrition Assistance Program began in 1982.

The block grant is based on regulations implemented through a Memorandum of Understanding that is revised every year. Like the Food Stamp Program in the fifty States, the Northern Marianas uses food coupons. However, it prints its own, earmarking 25 percent of them for products produced in the Northern Marianas.

5. What is the history of the Nutrition Assistance Program in the Northern Marianas?

There were several key pieces of legislation that led to the establishment of the block grant in the Northern Marianas.

P.L. 94-241, passed in 1976, provided the Northern Marianas with Commonwealth status. As a result, it became eligible for the same financial assistance programs that applied to Guam.

In 1978, P.L. 95-348 authorized the Secretary of Agriculture to implement a Food Stamp Program in the Northern Marianas. However, this authority expired in 1981 before a program was implemented.

P.L. 96-597 was then approved in 1980, authorizing the Secretary to extend programs administered by USDA to various territories. It also gave the Secretary the authority to waive or modify the requirements of those programs.

The preamble of the final rule implementing the block grant in the Northern Marianas cites both P.L. 94-241 and P.L. 96-597 as the underlying authority.

tps 5/10/93

Food Program Facts

Food and Nutrition Service
U.S. Department of Agriculture

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HELP FOR HOMELESS PEOPLE

May 1993

1. Do homeless people qualify for help from USDA's food assistance programs?

The U.S. Department of Agriculture's 14 food assistance programs are meant to provide a safety net to people in need. Low-income, homeless people and families may qualify for any of the programs. Food stamps, supplemental foods, commodity foods, and meals at school are available to homeless people just as they are to any person who qualifies. Local and State welfare agencies can advise people about their eligibility.

2. How many homeless people participate in the programs?

No good estimate exists of the number of homeless people who participate in USDA's food programs. Homeless people are not asked to identify themselves as homeless in their applications for program benefits.

3. Are there any food assistance programs especially for homeless people?

There is no USDA program specifically designed to help homeless people. However, USDA's Food Distribution Program for Charitable Institutions donates food to soup kitchens, shelters and food banks that regularly provide meals to homeless people. The Emergency Food Assistance Program (TEFAP) provides food to local public and private agencies for direct distribution to low-income people, including the homeless. USDA will donate nearly \$200 million worth of food in 1993 to programs that assist homeless people directly with meals or direct food distribution.

In addition, several of USDA's programs have specific provisions for homeless people:

- Recognizing that homeless people may have problems transporting and storing large amounts of food, regulations allow for States to permit participants in the Special Supplemental Food Program for Women, Infants and Children (WIC) to purchase foods in smaller packages and to shop more frequently.
- States may opt to substitute WIC food items that do not require refrigeration and are simple to prepare. For example, canned beans could be substituted for dried beans; canned juice for frozen juice; or ready-to-feed formula for powdered formula. State and local WIC agencies must provide nutrition education to help homeless WIC participants improve their diets and prepare nutritious meals using the substituted foods.
- State WIC agencies are required to include organizations serving homeless women and children in their regular outreach efforts, to let them know they may be eligible for the program.

Food Program Facts / Help for Homeless People

- Restaurants that offer low-cost meals to homeless people may accept food stamps. Participating restaurants contract with States to provide meals to homeless patrons. Some shelters and soup kitchens also accept food stamps as payment for the meals they serve.
- USDA food program regulations allow people with no fixed address to receive benefits from the programs.
- Homeless people may qualify for expedited service that provides them with food stamp benefits within five days.
- Homeless shelters that provide licensed or regulated child care services may be eligible to participate in the Child and Adult Care Food Program, which provides commodity foods and cash reimbursements for meals and snacks served.
- For all child nutrition programs (the National School Lunch Program, the School Breakfast Program, the Summer Food Service Program, the Special Milk Program, the Child and Adult Care Food Program), shelter directors and local officials may complete applications for free and/or reduced price meals on the child's behalf when applications are not submitted by the household. School districts can transfer a student's free or reduced-price eligibility to another school in the same district without any need to re-apply. Children from households that have no income can be temporarily approved to receive free lunch and breakfast.
- Organizations that conduct regularly scheduled food service primarily for homeless children or families may participate in the Summer Food Service Program. This program provides reimbursement for up to two meals per day for each child 18 years of age and younger.
- Homeless shelters not participating in other Child Nutrition programs may participate in the Special Milk Program. The Federal government will reimburse the actual cost of the milk provided free to eligible children.
- The Department of Agriculture is conducting the Child Nutrition Homeless Demonstration, which provides reimbursement for meals and snacks served to preschool age children in shelters.

4. What other efforts has USDA developed to help homeless people?

The Department has awarded a series of small grants to non-profit organizations that are working to demonstrate effective methods of reaching homeless people and helping them make better use of the available USDA food assistance programs.

States and local WIC agencies have developed a number of successful local initiatives to reach potentially eligible homeless women and children. In one area, for example, a van patrolled locations frequented by homeless people, providing information about WIC to those who might be eligible.

USDA also participates in the Federal government's Interagency Council on the Homeless.

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FIGHTING FOOD STAMP FRAUD

May 1993

1. What is food stamp fraud?

The Food Stamp Program will provide more than \$22 billion in benefits in Fiscal year 1993, and will serve more than 27 million people each month. In such a large program, it is perhaps inevitable that some people will violate the rules in an effort to get benefits they do not deserve, or to divert benefits from their intended use.

The Federal government and the States have a wide array of methods in place to detect the different varieties of fraud, and to catch and punish people who intentionally abuse the Food Stamp Program. Those who do are regularly caught and punished either by disqualification from the program, or by heavy fines or jail terms.

Fraud is a broad term that encompasses several types of Food Stamp Program abuse, but it also applies to a specific type of program abuse. The Food and Nutrition Service (FNS) is the agency of the U.S. Department of Agriculture charged with administering the Food Stamp Program at the Federal level. FNS draws distinctions between three types of abuse:

- **Falsifying applications** - Food stamp fraud can be committed when either recipients or retailers intentionally provide false information when applying to participate in the Food Stamp Program. Recipient fraud occurs when individuals intentionally provide false information on their applications either to qualify for food stamps or to get more food stamps than they should be entitled to. Retailer fraud occurs when retailers falsify their applications to become authorized by USDA to accept food stamps.
- **Trafficking** - involves the sale, purchase or barter of food stamps for cash or other non-food items. Traffickers often obtain food stamps from recipients at a substantial discount of their face value. The most serious of food stamp violations, trafficking is committed by recipients and retailers, as well as people who have no legal right to use, acquire or possess food stamps.
- **Misuse** - eligible recipients and authorized retailers misuse the program when food stamps are knowingly exchanged for ineligible items, or are used for making multiple small purchases in order to accumulate cash change. A less serious but more common type of food stamp abuse, this kind of fraud can still lead to sanctions against a retailer or a recipient.

2. How does USDA ensure that states issue food stamp benefits accurately?

FNS works closely with the States to ensure that all program benefits are issued accurately. Accurate issuance ensures program integrity, which is the core issue behind program fraud. FNS provides technical assistance and incentives to the states to support their efforts to promote accuracy and issue benefits correctly.

Food Program Facts / Fighting Food Stamp Fraud

FNS established its Quality Control, or QC system to monitor the accuracy of food stamp eligibility determinations, and to ensure that households receive the correct level of benefits. Quality Control is accomplished through a system of worker training, reviews and financial incentives based on state payment accuracy. Under the QC system, states receive enhanced administrative funding for achieving low error rates; they can also be held liable for the funds they issue in error if they exceed a certain standard of accuracy.

3. Are benefits sometimes issued incorrectly?

To qualify for food stamps, applicants must meet certain eligibility requirements and provide proof of household circumstances. State certification workers evaluate each application to determine eligibility and to issue the proper level of benefits. Despite all the precautions, however, food stamp benefits are sometimes mistakenly issued to people who don't qualify for them. On the other hand, errors may sometimes mean that people don't receive all the benefits to which they may be entitled.

In most cases, overissuance or underissuance occurs because of an error on the part of either the applicant or the State certification worker who takes applicant's information. In only a relatively small percentage of cases are benefits issued incorrectly because an applicant has intentionally provided false information.

There are three ways an error can lead to an overpayment or underpayment of benefits, or incorrectly make a household eligible for benefits:

- **State agency error** is an error made by a State agency eligibility worker while taking an application or determining the level of benefits. This usually occurs when the worker miscalculates, does not correctly apply the regulations or does not get the necessary information to make a correct determination.
- **Inadvertent household error** occurs when a household inadvertently gives incorrect or incomplete information during the initial application process or after a client is on the program. This most frequently happens when there is an unreported change in household composition or income.
- **Intentional program violation** is an error made because the applicant intentionally provides inaccurate or incomplete information resulting in an overissuance of food stamps. This type of error constitutes recipient fraud.

4. Who investigates fraud by food stamp recipients?

Under Federal regulations, the State agency is responsible for investigating and prosecuting individuals suspected of recipient fraud or misuse. The U.S. Department of Agriculture's Office of the Inspector General (OIG) assists the States in some cases, especially when an interstate investigation is needed or if a caseworker is suspected of fraudulent activity.

Through anti-fraud funding, FNS offers States incentives to increase their fraud control activities. States are reimbursed up to 75 percent of their investigative expenses and are allowed to keep a percentage of the money recovered as long as the money was not lost due to State-committed error.

In Fiscal year 1992, States conducted more than 430,000 investigations of suspected recipient fraud.

Food Program Facts / Fighting Food Stamp Fraud

5. How do States catch and prosecute recipients who commit food stamp fraud?

States have the authority to conduct, at their discretion, a pre-certification investigation of a food stamp applicant. States have a number of ways to check records to ensure that applicants have provided accurate information, that they have not been disqualified from the program, and that they are not receiving food stamp benefits in more than one location. States may look at tax and employment records; marriage, birth and death records; school records or other sources.

In addition, all states are required to establish a system to conduct computer matches with other State systems and the Federal government. FNS is in the process of implementing the **Disqualified Recipient Subsystem**, a new electronic information system that tracks information on individuals who have been disqualified from the Food Stamp program for intentional program violations. DRS enables States to identify individuals who intentionally violate program rules, and to apply progressively stringent penalties for multiple violations. Recipients found guilty of an intentional program violation are disqualified from the program for 6 months for a first violation, 12 months for a second violation, and permanently for a third.

States may also use the DRS to screen new applicants and current food stamp recipients to ensure that those currently in a disqualified status do not participate until they have completed their penalty. About 20 States are expected to begin using the DRS by June 1993.

States may choose one of three methods to prosecute recipients who abuse the program. In Fiscal Year 1992, more than 72,000 recipients were disqualified as a result of one of these three processes:

- **Criminal prosecution** - Cases can be referred for prosecution when a high dollar amount is involved; or when people within the system, such as a State or local agency employee, are involved; or when the recipient has previous violations; or when other flagrant violations have occurred.
- **Disqualification Consent Agreement (DCA)** - An alternative to prosecution, a DCA occurs when State prosecutors have very clear evidence of fraud and offer the client an opportunity to avoid a possible prosecution, saving time and money. In voluntarily accepting the terms of the agreement, the recipient is disqualified from the Food Stamp Program and must repay any over-issuance.
- **Administrative Disqualification Hearing (ADH)** - Another alternative to prosecution, an ADH is a non-criminal hearing to determine whether an individual has intentionally violated program regulations. If found guilty, the recipient will be disqualified from the Food Stamp Program and required to pay back any overissuance.

6. What are the penalties for recipients who commit food stamp fraud?

Recipients found guilty of an intentional program violation are disqualified from the program for 6 months for a first violation, 12 months for a second violation, and permanently for a third. Fines up to \$10,000 or imprisonment up to 5 years can also be applied. Recipients involved in large-scale trafficking may be liable for tougher penalties.

Food Program Facts / Fighting Food Stamp Fraud

7. Can USDA recover funds that are issued in error?

People who receive food stamp benefits they do not deserve are required to repay them, whether the issuance occurs through fraud or inadvertent error. If the debtor is still receiving food stamp benefits, the monthly allotment may be reduced slightly every month until the overpayment is paid back. States also use other means to recover erroneous payments, especially when the debtor is no longer receiving benefits. Every year, States collect millions of dollars worth of overpayments by such means as billing letters, collection agencies, small claims court and wage garnishment.

In cases where the debtor is no longer participating in the Food Stamp Program and the money cannot be recovered by conventional efforts, the tax intercept program provides another means to make people pay what they owe. Tax intercept is a cooperative effort between USDA and the Internal Revenue Service to collect food stamp overpayments. Under the program, overpayments owed to the Federal government may be deducted by the IRS from an individual's income tax refund. Claims resulting from State agency errors are not referred for intercept.

In 1992, tax intercept pilot programs in California and Alabama collected \$3 million from people who had left the food stamp program while still owing benefit repayments. The program has expanded into seven more states in 1993, and will add another 14 states in 1994.

States collected more than \$34 million in recipient fraud claims in FY 1991.

8. How big a problem is trafficking?

There is no way to estimate accurately how many dollars worth of food stamps are involved in food stamp trafficking every year. FNS redeems food stamps returned through the Federal Reserve system, and has no way of knowing whether the stamps have been involved in fraud or trafficking between the time they were issued and the time they were redeemed. FNS is working in all parts of the United States to eliminate trafficking.

Trafficking is a serious problem in part because it erodes public confidence in the Food Stamp Program. Television reports have shown recipients and retailers readily buying and selling food stamps for cash. Even though the vast majority of recipients and retailers are careful to follow the program's rules, these reports have left some people with doubts about the program's effectiveness.

The vast majority of merchants do abide by the program's regulations. Supermarkets make up about 15 percent of all authorized food stamp retailers, but handle almost 75 percent of all food stamps redeemed. Generally, these larger stores have adequate internal controls in place to prevent program abuse. Among smaller stores, the majority also are careful to follow program rules. Still, an unscrupulous retailer must be involved if trafficked food stamps are to be redeemed for their face value.

9. Who investigates trafficking by retailers or recipients?

Both FNS and USDA's Office of the Inspector General (OIG) place major emphasis on identifying retailers who abuse the program. In 1992, FNS allocated more than \$3.7 million to retail investigation. Another \$1 million went into a project to begin re-authorization of all of the program's 213,000 retailers, and to update information in the computer database that keeps track of retailers.

FNS field offices monitor authorized retailers for program compliance and refer cases of suspected abuse to either USDA's OIG or to FNS, depending on the level of illegal activity.

Food Program Facts / Fighting Food Stamp Fraud

The FNS Compliance Branch maintains a core staff of 54 investigators whose full-time work is to investigate suspected retailer violations. In fiscal year 1992, investigators tracked more than 4,800 cases of suspected food stamp abuse. Of those, more than 2,000 discovered violations and more than 1,400 warranted retailer disqualification. Retailer trafficking was discovered in more than 750 of these investigations.

The OIG has the primary responsibility for investigating suspected large-scale criminal activity by authorized retailers. The OIG initiates investigations based on information from FNS, other law enforcement agencies or citizen complaints to the OIG hotline. Depending upon the type of criminal activity, other Federal enforcement agencies such as the Postal Service or Secret Service could become involved.

States are responsible for investigating recipients suspected of trafficking, and are eligible for enhanced funding for any efforts the State undertakes to identify those selling food stamps.

10. What are the penalties for trafficking in food stamps?

Prosecutions for authorized retailers charged with trafficking are handled by Federal prosecutors, or by State and local prosecutors in States that have specific food stamp trafficking statutes. At the Federal level, retailer trafficking cases can be handled through criminal prosecution or through civil prosecution under the False Claims Act.

Not all offenders are penalized through prosecution. Depending on the severity of the crime, FNS can disqualify the retailer as well as impose severe administrative penalties and fines.

There are also provisions for disqualification of recipients who traffic in food stamps, and recipients could be liable to criminal or civil penalties for large-scale trafficking.

11. What is being done to combat trafficking?

The 1990 Farm Bill provisions

The program provisions of the 1990 Farm Bill now help USDA crack down on criminals by stiffening the penalties and improving the integrity of retailer operations. Some of the new rules:

- Double the maximum civil money penalty for firms caught trafficking in food coupons or other benefit instruments, from \$20,000 to \$40,000 per case.
- Fine unauthorized people who accept and redeem food stamps \$1,000 for each violation plus an amount equal to three times the value of the coupons accepted.
- Fine stores that accept loose coupons \$500 each time they are caught, plus an amount double the value of each coupon illegally accepted.
- Make unlawful use of \$5,000 or more in coupons, authorization cards or access devices a felony punishable with a maximum fine of \$250,000 and/or 20 years in prison.
- Initiate a major re-authorization of retailers to collect new, updated information including social security and employer identification numbers.

Food Program Facts / Fighting Food Stamp Fraud

Working with States

FNS has begun working with States, urging them to engage the cooperation of local law enforcement officials to address blatant trafficking that occurs outside some food stamp issuance sites. This approach has succeeded in some cities. Additionally, FNS has held a series of meetings with States to discuss a cooperative initiative toward reducing trafficking. If this proves to be successful, it may encourage more States to take an active approach to street trafficking. FNS can provide 75 percent of the funding for this kind of anti-fraud activity.

FNS has worked for several years with States to encourage the passage of State food stamp fraud statutes, and most States now have such laws in place. Specific State criminal statutes add more watchdogs to the system by enabling local investigators and prosecutors to monitor compliance in their State and penalize those found guilty of abuse.

Civil prosecutions

FNS and the Office of the Inspector General are working closely with the Civil Division of the U.S. Attorney's Offices around the country to increase the number of civil actions against retailers caught trafficking. These actions are brought under the False Claims Act, and can result in significant financial liabilities for retailers. Monies collected in these civil actions are returned to the Federal Treasury.

Electronic Benefits Transfer

EBT holds great promise as a method of reducing food stamp trafficking, though it is still not in widespread use. EBT is an electronic system for transferring money from a recipient's food stamp account to a retailer's account. Instead of using paper food coupons, recipients draw their benefits directly from their food stamp account by using a plastic "debit card," similar to a bank card.

The EBT system has several advantages over the paper coupon system, including the reduction of theft or card loss through security measures like the use of a Personal Identification Number (PIN) with each card; the elimination of mail theft; and the ability to freeze recipient accounts once a card is reported stolen. EBT also creates a "paper trail" that documents each food stamp transaction, making it easier to trace abuses by either the retailer or the food stamp recipient. In addition, the use of EBT eliminates cash change, which is often spent on goods other than eligible food items.

EBT is being tested in five pilot projects across the United States, and so far the response has been positive. While the conversion to EBT will not eliminate all trafficking, properly designed and implemented EBT systems will greatly reduce program abuse. Through the use of EBT records, FNS will be better able to monitor and analyze food stamp sales activity at authorized retail stores.

12. What should someone do who knows of food stamp abuse?

Fraud or trafficking can be reported to USDA's Office of the Inspector General at 1-800-424-9121. State and local law enforcement officials can also be contacted. To reach the Food and Nutrition Service's enforcement authorities, write to Food and Nutrition Service, USDA, Food Stamp Division, Compliance Branch, 3101 Park Center Drive, Alexandria, Virginia, 22302.

Food Program Facts

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ELECTRONIC BENEFITS TRANSFER

May 1993

1. What is Electronic Benefits Transfer?

Electronic Benefits Transfer (EBT) is an electronic system for transferring money from a food stamp or other public assistance account to a retailer's account. Food stamp customers make purchases by using a plastic "debit card" at store terminals to access their available benefits.

2. How does EBT work?

Under the EBT system, food stamp users apply for their benefits in the usual way, by filling out a form at their food stamp certification office. Once their eligibility and level of benefits is determined, an account for their food stamp benefits is established in their name and they are issued a plastic EBT card. Recipients are taught how to use the card, and they choose a personal identification number (PIN) to use with it.

When paying for groceries, the food stamp customer's card is run through an electronic reader, they enter their PIN, and their food stamp account is debited for the amount of the purchase. A receipt is provided showing the amount of purchase and the amount remaining in the benefits account. No money and no food stamps change hands, and all the accounting work is done automatically by computer. Money debited from the customer's account for food stamp purchases is credited to the retailer's bank account within a few days.

3. Is this new technology?

EBT is a special application of the technology called Electronic Funds Transfer, or EFT. It is a "debit card" system, which takes money directly from one account and transfers it to another. (Credit cards, by comparison, simply record a sale for payment later.) EFT became familiar to most people in the early 1980s when banks began using automatic teller machines. Since then, EFT has found increasing use in the private sector.

The Department of Agriculture's Food and Nutrition Service (FNS), which administers the Food Stamp Program, has been one of the most active Federal agencies in the field of EFT/EBT. FNS began its first experiment with EBT in 1984 in Reading, PA. That system is still operating, and other projects have been added. FNS has also sponsored a small pilot project using EBT to issue benefits in its Special Supplemental Food Program for Women, Infants and Children (WIC).

4. How many assistance programs are using EBT?

USDA's Food Stamp Program and WIC Program, the Department of Health and Human Services' Aid to Families with Dependent Children (AFDC) program, and some States' Child Support Enforcement programs have made use of EBT technology.

Food Program Facts / Electronic Benefits Transfer

5. What are the advantages of EBT?

The Food Stamp Program uses 2.5 billion coupons each year. They are handled by 213,000 retailers, who make 2 million deposits each month in 10,000 financial institutions. Banks in turn make more than 40,000 food stamp deposits each month in the Federal Reserve District Banks. Coupons are counted at each step in the cycle, and the accounting is enormously complex. EBT eliminates much of the paper handling involved in the food stamp system, and automates much of the accounting.

Advantages to the recipient, the retailer, the banker, and the Federal government include:

- Recipients like the convenience and security of EBT. They no longer have to go to the food stamp issuance office to pick up their food stamps, and there are no coupons to be lost or stolen. They can draw their benefits as needed instead of receiving a month's allotment at one time. If the card is lost or stolen, it can't be used by anyone who doesn't know the PIN, and it can be easily canceled and replaced. Surveys have shown that most participants prefer an EBT system to the paper coupon system it replaced.
- Retailers like the simplicity of accounting and not having to handle the food stamp coupons. They save labor costs by not having to sort, count, and bundle the coupons to deposit them at the bank. All the accounting in food stamp transactions is done automatically. Finally, there is no need to give cash change. Recent studies showed that, overall, costs for retailers participating in the Food Stamp Program dropped 25 percent (from \$24 per \$1,000 of benefits redeemed to \$18 per \$1,000).
- Bankers like the system for many of the same reasons retailers do: labor costs are saved by the elimination of paper food stamps and by the automatic accounting.
- Federal officials also save time and labor in the accounting process, plus the costs involved in printing, transporting, safeguarding, distributing, and finally destroying the food stamps. Opportunities for theft and some kinds of fraud and misuse of food stamp benefits are reduced, thus helping to ensure that benefits go to buy food for people who need it.

6. What are the problems?

The primary problem with EBT, that of cost, has been overcome. Initially, EBT systems were more expensive to operate than conventional food stamp issuance systems. EBT reached a milestone in June of 1993, however, when evaluations of EBT projects in New Mexico and Minnesota showed that both cost less to operate than the estimate of what each site's paper coupon issuance costs would have been in the same time period. EBT/EFT costs are expected to continue to diminish as the technology becomes more widely used.

7. What's the cost?

States implementing new systems are expected to operate on a "cost neutral" basis, meaning that EBT systems should cost no more to operate than the traditional coupon system. The most recent demonstrations showed that, under an EBT system, administrative costs per case month dropped from \$4.04 to \$3.07 in New Mexico and from \$4.53 to \$4.38 in Minnesota. Costs were also reduced for retailers, recipients and financial institutions.

The Federal government has routinely shared Food Stamp Program operating costs with the States, including the costs of EBT up to the cost of conventional coupon issuance systems. The

Food Program Facts / Electronic Benefits Transfer

Federal government paid 100 percent of development costs in the initial Reading project, and continues to share operating costs with the State up to the cost of the conventional food stamp system. Total Federal costs to get the Reading system up and running were about \$3.3 million. Operating budgets for more recent rounds of demonstration projects have been funded on a similar basis.

The 1990 Farm Bill provided that States could develop on-line EBT systems as an operational alternative for food stamp issuance. USDA published regulations in April, 1992, for the EBT alternative. The regulations require that all State EBT systems meet a standard for cost neutrality.

8. What has been done so far?

Many States are considering using EBT as an operational alternative for food stamp issuance, and possibly for other programs such as USDA's Special Supplemental Food Program for Women, Infants and Children (WIC), and the Department of Health and Human Services' Aid to Families with Dependent Children (AFDC) program.

- **Pennsylvania:** The Reading, PA, demonstration project has been operating since 1984. FNS determined from that project that EBT was technologically feasible, that it was liked by almost everyone involved, and that it was more expensive than the conventional system. New generations of tests have been planned with an eye to reducing costs.
- **Maryland:** Maryland's Independence Card system, the nation's only statewide EBT system, became operational in Maryland in April 1993. The system, initiated as a pilot program in Baltimore in November 1989, allows participants access to food stamps, AFDC and general assistance benefits. It is also the first application of EBT to Federal and State child support enforcement payments. Approximately 150,000 Maryland households receive food stamp benefits through EBT at 3,200 retail stores. Participants in cash benefit programs can receive their benefits at any automatic teller machine in the MOST system.
- **Minnesota and New Mexico:** Two additional EBT demonstrations have been implemented in Ramsey County (St. Paul), Minnesota and Bernalillo County (Albuquerque), New Mexico. Both tested on-line multiple-use systems, including commercial transactions, AFDC and other cash assistance programs, and food stamps. The emphasis was on designing an EBT system that will reduce costs and improve operations. New Mexico began operations in September 1990, and Ramsey County in September 1991. As noted earlier, studies found EBT to be cost effective, and both sites plan to continue operations.
- **Ohio:** The first project to test "off-line," or "smart card" technology began operation in Dayton (Montgomery County), Ohio, in March, 1992. The off-line system uses an integrated circuit card, or "smart card," with a micro processor chip embedded in the card. The chip contains all the information needed to authorize food stamp purchases. The retailer records purchases on the card, and can report food stamp transactions periodically in batches, rather than accessing a computer for each purchase as with on-line systems. The off-line demonstration project in Dayton includes an average of about 12,000 food stamp households served by approximately 80 retailers. The main goal of the demonstration project is to test off-line system technology in terms of acceptability to recipients, retailers and financial institutions, as well as cost effectiveness for the Federal government.

Food Program Facts / Electronic Benefits Transfer

- **Wyoming:** The first project to test the application of EBT in the WIC program. A small pilot project was completed in the summer of 1992. An expanded test, using a single "smart card" to issue WIC and Food Stamp Program benefits, is being planned in Wyoming. The State plans to expand the system to cover more WIC households and to integrate with the Food Stamp Program.
- **South Carolina:** South Carolina is preparing to start a pilot project in Darlington County for food stamp issuance. The state expects to award a contract to develop their system very soon.
- **New Jersey:** New Jersey will begin testing EBT for food stamp and AFDC issuance in Camden, Essex and Hudson Counties. Implementation is expected to begin in Camden in early 1994, and all three counties are expected to be on line by April 1996. New Jersey's projects have been designated a demonstration, so an evaluation will be required.
- **Texas:** Texas is planning an EBT issuance system for medical, cash and food stamp benefits, to be piloted in Harris and Chambers Counties. The State expects to award a contract for development of the system in November of 1993, and to issue the first benefits electronically in May 1994.

9. What is the future for EBT?

As the number of States pursuing EBT increases, FNS will focus on finding ways to increase the efficiency and economy of those efforts. Continued emphasis will be placed on systems that can provide benefits for multiple assistance programs, and on "piggybacking" EBT on commercial EFT operations. In time, electronic issuance systems could be available nationwide.

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Food Program Facts

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CASH-OUT PROJECTS IN THE FOOD STAMP PROGRAM

May 1993

1. What does "cash-out" mean?

"Cash-out" means that Food Stamp Program participants receive their federal food assistance benefits in cash (actually by check) rather than in food stamp coupons.

2. What is the purpose of the cash-out projects?

The U.S. Department of Agriculture and its Food and Nutrition Service (FNS) agreed to conduct demonstrations of the cash-out concept as a welfare reform demonstration, and at the request of several states. The Department hopes the demonstration projects will provide some answers to long-standing questions about the best way to provide food assistance to needy people.

FNS funded the demonstration projects and evaluations to test cash-out as an alternative means of delivering food stamp benefits. FNS is also testing electronic benefits transfer (EBT) as a possible benefit delivery system, but it takes no position on the desirability or effectiveness of any of the alternative methods of providing benefits. Rather, the agency is looking at a variety of alternatives, each with its strengths and weaknesses.

3. What are the advantages of the coupon system?

Advocates of the current food stamp coupon system argue that it is a direct and inexpensive way to ensure that federal food assistance benefits are used to purchase food. Coupon advocates contend that despite some evidence of fraud and benefit diversion under the current system, unauthorized use of food stamps is relatively small. In addition, they argue, coupons provide some measure of protection to food budgets from other demands on limited household resources.

4. What are the advantages of cash-out?

Advocates of cashing out the Food Stamp Program argue that the current system is prone to abuse, limits the food purchasing choices of recipients and places a stigma on participation. They also cite the costs to federal, state and local governments and to retailers and banks in printing, storing, safeguarding, transporting, issuing, redeeming and destroying the food stamps.

5. What testing has been conducted so far on the cash-out concept?

FNS conducted two cash-out studies in the early 1980's: the Supplemental Security/Elderly Cash-Out Demonstration and the Puerto Rico Nutrition Assistance Program (Puerto Rico has provided cash rather than food stamps for food assistance since 1982). Both studies produced useful findings, but their findings were not applicable to the entire food stamp population.

Food Program Facts / Food Stamp Cash-Out Projects

Welfare reform initiatives in the late 1980's helped revive interest in cash-out. In their attempts to streamline welfare administration and save costs, several states proposed cashing out food stamp benefits for clients participating in their welfare reform demonstrations.

While the states initiated the cash-out demonstrations, FNS has taken on the responsibility for their evaluation. FNS approved four major cash-out projects for testing and evaluation:

- **Washington State Family Independence Program (FIP).** AFDC recipients who enrolled in randomly selected FIP community service offices receive their food stamp benefits in cash. Their household expenditures and food use will be compared with those of AFDC participants receiving food stamp coupons. The evaluation report is expected to be published in 1993.
- **San Diego Food Stamp Cash-Out Demonstration.** In July 1989, 20 percent of the food stamp caseload in San Diego County was cashed out. All food stamp households in the county were converted to cash food benefits on September 1, 1990. The report on household expenditures and food use was released in January 1993. A second report on the effects of cash-out on participation, administrative costs and food retailers is due for release in the fall of 1993.
- **Alabama Cash-Out Demonstration.** Approximately 2,300 households were randomly selected to be cashed out in 12 counties for a period of eight months. They were compared with an equivalent group of households receiving coupons. The results of the study evaluating the effect of cash-out on household expenditures, food use and administrative costs were released in January 1993.
- **Alabama Avenues to Self-Sufficiency through Employment and Training Services (ASSETS) Demonstration.** Households participating in three demonstration sites are being cashed out. They will be compared to a similar group in three sites not operating ASSETS. A report evaluating the impact on household expenditures and on retailers is due in the summer of 1993. A report on the effects of cash-out on food retailers is due at the same time.

6. How were the pilot projects evaluated?

As a first step in the evaluation, FNS assembled an advisory group of experts in food surveys, evaluation, sampling and data analysis. This group helped the agency develop an evaluation strategy, including random selection of project sites and households to participate in the individual studies.

The evaluation plan calls for assessments to be conducted at each site selected for the study. The sites themselves vary widely on a number of important characteristics, including size of average household benefits received, urbanicity, and availability of other assistance such as AFDC and General Assistance. San Diego and Alabama are "pure" demonstrations, meaning that only food stamp benefits are being cashed out, while Washington FIP and Alabama ASSETS are "mixed," meaning they operate in conjunction with other welfare reform efforts.

To ensure the uniformity and comparability of data across sites, FNS developed a set of core questions to be administered at all cash-out and comparison sites. This core package captures client information on expenditures, food use, household characteristics, experiences with cash and coupon benefits, and attitudes toward the two benefits forms.

The evaluations also considered the effects of cash-out on Food Stamp Program participation, program costs, community perception of the program, and on food retailers. Special problems that may be associated with cash-out also were examined.

Food Program Facts / Food Stamp Cash-Out Projects

7. What findings have been reported in the project evaluations so far?

Information now available from the demonstrations describes the short-term effect of cash-out on household expenditures, food use, nutrient availability and preferences. There is only limited information on administrative costs and retailer preferences and as yet no information on program participation. A more complete description of the effects of cash-out must await these forthcoming analyses. We can, however, draw some tentative conclusions about the effect of cash-out on food stamp households:

- Cash-out appears to reduce household food expenditures, but the size of the reduction remains uncertain. Three of the evaluations find statistically significant reductions in food expenditures. The reduction in San Diego is relatively modest (roughly 5 percent); the reduction in Alabama ASSETS is substantially larger (about 20 percent); and the reduction in Washington falls in between (about 15 percent). In the other Alabama test, however, there is virtually no difference between households with checks and coupons.
- There is some evidence that cash-out reduces the availability of some nutrients. It is not clear, however, that households receiving checks are at significantly greater nutritional risk. San Diego and Washington evaluations noted some modest reduction in intake of food energy, protein and some nutrients. The Alabama cash-out test reported virtually no difference in nutrient availability between check and coupon households. The Alabama ASSETS evaluation did not collect food use data.
- There is little evidence of any increase in households reporting they do not have enough to eat, or that they are skipping meals, or that there are days when they are without food or resources to buy food.
- There is some evidence that cash-out leads to higher expenditures on some items other than food. San Diego, Washington and Alabama ASSETS all reported significant increases in the share of household budgets devoted to shelter. The other Alabama test reported virtually no difference between check and coupon households. Some tests reported increased shares devoted to transportation, medical and educational costs.
- Households that receive checks prefer them to coupons.

8. How long will the demonstration projects go on?

The studies underway are demonstrations with finite time limitations. FNS currently has no plans to convert any of the demonstrations to permanent operations. For example, households participating in the Alabama Cash-Out Demonstration reverted to coupon benefits on January 1, 1991. The remaining demonstrations are scheduled to return to coupon issuance by 1994.

Mr. DURBIN. Mr. Skeen.

Mr. SKEEN. Thank you, Mr. Chairman.

And once again, it is delightful visiting with you folks this morning because I think that the Disaster Task Force that we have here in Congress will be very much interested in the experiences that you went through in the Los Angeles disasters. I think it is a good format for avoiding that kind of problem in the future in some segment of this disaster equation that we have not really dealt with before.

HUNGER IN AMERICA

Let us go back to the nutrition discussion. We have got 15 programs feeding people in this country. A lot of them overlap, and I am always amazed that we are so focused on hunger that we keep, I think, beating ourselves over the back about how we are not feeding people in the United States. With these programs there is no reason why someone should go hungry.

Am I mistaken in that? Are there some spaces or cracks in the floor, or is there something wrong with the whole spectrum that we are dealing with?

How is the coordination between all of these programs and so on? Just give me an overview of how you feel about that.

Ms. HAAS. Well, to begin with, it is an unfortunate reality that hunger still does exist in certain places today. Many times access to food assistance is limited because people face barriers. Sometimes that falls heaviest on the elderly and on children.

I think the Mickey Leland Hunger Prevention Act will go a long way in addressing some of those barriers that we had in our own policies, where we did not fully take into account shelter costs, and we also did not give incentives to people who went back to work, such as child care deductions. So I think that we included many important provisions in the bill, which are revising the Food Stamp Program to make sure that greater access exists.

Also, there are many people, particularly the rural poor in many counties, who need outreach in order to start getting food stamps; so the outreach grants that we have had have made a positive difference.

The coordination among the food assistance programs is based in the Office of Food and Nutrition Service. I think we have to take a look again at these programs, and through the child nutrition reauthorization process, for example, look at the several child nutrition programs to see how we can bring more conformity in the kinds of eligibility rules that we have as well.

I think that your major question is if we have 14 programs, why do we still have hunger.

Mr. SKEEN. I think we have 15 programs.

Ms. HAAS. Fifteen programs. What we are really talking about is that hunger reflects the state of the economy. And as the economy gets better, as unemployment goes down, and you continue the safety net, we continue to address the problem of hunger. I think that the Administrator probably can add to that about the coordination, which is what I think your specific question is.

COORDINATION AMONG FOOD ASSISTANCE PROGRAMS

Mr. SKEEN. Yes, Mr. Ludwig, I would like to hear that.

Mr. LUDWIG. Yes, sir.

We are looking at all of our programs, not only the programs with—

Mr. SKEEN. Let me interrupt you just a moment here.

Do you have access to all these programs under the purview of your administration?

Mr. LUDWIG. Fifteen, yes.

Ms. HAAS. Right.

Mr. DURBIN. So they are not disassociated from you?

Mr. LUDWIG. No, sir.

Mr. SKEEN. Okay.

Mr. LUDWIG. No, sir. We have them all. They all fall under—

Mr. SKEEN. They all fall under your purview?

Mr. LUDWIG. Yes, sir, they do.

We are also looking at some of the other programs within HHS like the AFDC program, and we are trying to coordinate with them to make sure we are covering all eligible people.

But as far as our programs, many people are eligible for multiple programs, like the elderly, for example. They are eligible for food stamps. We make a lot of provision within the Food Stamp Act just for the elderly population. At the same time they are eligible to go to the NPE program and have lunches, too. So we are trying to coordinate the programs to make sure that the needs of eligible people are covered and access is there.

Mr. SKEEN. You mentioned barriers and outreach. I think those are some of the elements that you discussed. People come to my district offices asking for food when they have problems and assistance because they don't know where to get the help. It has been a tremendous problem.

Ms. HAAS. This year when Secretary Espy first came to office, he started a whole process of doing forums. The first forum we had was a national hunger forum where we brought together the largest number of people who were expert in the area of hunger since the White House Conference on Nutrition back in 1969. We had over 300 experts, and they spoke about access to the various food assistance programs.

We can work with you in getting that information to your offices as well, because the various programs have grown up and Congress has authorized them or established them because of a need that has existed. What we do is really divide the programs by almost every age group, starting with WIC and moving all the way through the nutritional program for the elderly. We would be happy to provide additional information to your offices of where people can go for food assistance.

What is different about our programs is that they are administered at the state level by other agencies. Food stamps are administered by the welfare or social services offices; child nutrition programs, by education; and WIC, by the health departments. So that kind of coordination with a number of State agencies is very important, and it is the key to maintaining our partnerships with state agencies that do not report to the Department of Agriculture.

Mr. SKEEN. Well, we need to educate ourselves as far as being helpful to people, but it always amazes me that we focus on hunger in a country as well off as we are. First of all, the agricultural community provides the most nutritional foods and we have 15 USDA programs to distribute some of it to the hungry.

Ms. HAAS. Well, we do want to provide it. In fact, we are doing our next hunger forum in Dayton with Congressman Tony Hall, who is leading this effort.

Mr. SKEEN. Well, that is very important. Let me focus now on the food stamp fraud. You mentioned the Albuquerque program, and we have already been hearing about some attempts to defraud the system that have cropped up in the Albuquerque experience.

FOOD STAMP FRAUD AND ELECTRONIC BENEFIT TRANSFER

What would that encompass? What was the problem there? Was it misuse of the card, giving the card to someone else? I think that was the one cited to me.

Ms. HAAS. Again, going back to the retailers. Fraud occurred if the retailer accumulated EBT cards or bought EBT cards. That's why it is important to recognize that we are not eliminating fraud.

Mr. SKEEN. No, no.

Ms. HAAS. We are significantly reducing food stamp trafficking, and in EBT sites food stamps are no longer being used as a currency on the street, to sell for drugs and guns the way food stamps are today.

Mr. SKEEN. Well, it is far more difficult to defraud the system, if I understand what Mr. Ludwig is saying—

Mr. LUDWIG. There is a paper trail.

Mr. SKEEN. Well, a paper trail, but you also get profile on retailers.

Mr. LUDWIG. Yes, let me give you an example.

Mr. SKEEN. And I think that is extremely important.

Mr. LUDWIG. Right.

If you gave your card to me, or sold your card to me and I went into a grocery store, I would swipe it one time and receive all the benefits at once instead of using those benefits over a month at \$30 or \$40 or \$50 at a time. I would just withdraw \$350 or \$360 at one time. Those are the types of profiles we do on stores, to see what the percentage is for one time usage of a card. We find that those stores that are involved in trafficking normally have very high percentages for one time usage, and we use the profiles to target them.

Mr. SKEEN. So immediately they crop up when you recross the profile.

Mr. LUDWIG. We do a profile, and anything outside the profile is suspect.

Mr. SKEEN. This is becoming far more cost-effective in the long run.

Mr. LUDWIG. We will have some results on EBT out within the next 30 to 45 days of some pilots that we have going. We have found that EBT has led to substantial savings for the U.S. Government, even more so than the state government. The state governments do not recognize quite as much savings as we do. We have found savings from the recipients' standpoints, and have found that the retailers love it. Specifically EBT has an impact on the amount

of funds that are being lost through trafficking that never make their way to legitimate retailers.

Ms. HAAS. It is important—there is a state-wide program of EBT in the State of Maryland.

Mr. SKEEN. We understand that.

Ms. HAAS. What they have found is that the trafficking has been significantly reduced. They also have seen a reduction in administrative costs associated with issuing the food stamps.

There is an interagency task force on EBT which is preparing a report to the Vice President at the end of March or beginning of April. Working with other agencies gives us an opportunity to build into our EBT system fraud prevention. In the Food Stamp Program in the past we were dealing with problems after they occurred.

We now have an opportunity with the planning of EBT to set up preventive mechanisms so that we can reduce fraud even more.

Mr. DURBIN. Will the gentleman yield?

Mr. SKEEN. Yes, sir.

Mr. DURBIN. While we are on the subject, I am sure that you have pored over our report which accompanied the 1994 appropriations bill last year and you may have noted at one point that we asked for a report on the Maryland program by March 1. I am sure it is in the mail. [Laughter.]

Ms. HAAS. The final report should be available later this spring.

Mr. LUDWIG. That is the report I am talking about. We have already gotten some of the preliminary findings, and it also includes New Mexico.

Mr. SKEEN. Well, I would appreciate you keeping us advised on it.

DIETARY GUIDELINES IN THE NATIONAL SCHOOL LUNCH PROGRAM

Let me move to just one area. You mentioned the School Lunch Program. The WIC Program is so important to us because that is the start of it. We are carrying this nutritional thing through the whole life span pretty well. And what I am concerned about the School Lunch Program and the lack of, I think, enough coordination, but cooperation that you are getting from some of these sources.

The school lunch people come to us and they want full funding for the School Lunch Program. Fine. I can understand that.

But then also when I hear the menus over the television in the morning when I get up and decide which road I am going to take to try to get back into D.C., those menus are horrible. No wonder those kids will not eat that stuff. And I do not know whether it is because of the lack of availability, or lack of funding, or the lack of availability of good nutritional foods, or it is just on the part of those who prepare it. That is an easy way to do it and that is supposedly popular to the youngsters. But some of the stuff that they are feeding those kids, if I read the menu, I would not go to school.

What kind of mandates do you have? And I hate for us to initiate mandates into these programs because we fund them, then we want to mandate them.

Ms. HAAS. Let me share with you, Congressman Skeen, that I went back, and I read your big committee's report last year. But

I also went back to the National School Lunch Act in 1946, which was established by President Harry Truman.

The School Lunch Program was enacted to ensure the health and well-being of children.

Well, since 1946, our nutritional knowledge has tremendously increased, and we now know about the link between diet and health. However, since the 1940s we have not updated our nutrition requirements. We are still practicing 1940s nutritional knowledge in our basic policies for the Department of Agriculture.

That is why we went through a hearing process that has been very inclusive, where we heard testimony from the presidents of the American Heart Association and the American Cancer Society, the Surgeon General, food service professionals, doctors, and students, all calling for a change to meet these Dietary Guidelines.

When we make changes, we also believe that we have to emphasize taste and appeal if children are going to get the benefits.

Mr. SKEEN. There is no question about it.

Ms. HAAS. And educating about food choices. We would like to share with you more of the future directions that we hope to go. That is why it is so important for us to have this small amount of money that is in the budget for nutrition, education, training and technical assistance.

Mr. SKEEN. But you are in the process of making those changes—

Ms. HAAS. We hope to make those changes.

Mr. SKEEN [continuing]. Over the 40 hearings.

Ms. HAAS. In the hearings that we have had, we have said that we have got to meet Dietary Guidelines as a way of helping children. We've put a great emphasis on accountability in the School Lunch Program, but the paperwork just grew and grew and grew. What we've forgotten is the basis of this program, the health of children. And that's what we are in the process of changing.

Mr. SKEEN. I think that is a good response, and also when you mention the paperwork, I am glad that you are sensitive to the problem. Because most of the folks in nutrition, dietetic consulting, and so forth do not even get into the diet end of the thing, because they have got so doggone many reports to do.

Ms. HAAS. Well, that's why I said you've got to change what's on the plate. We've got to have an integrated approach. We've got to take into accounts the tastes and appeal and education of children at the same time we are making sure that the program is accountable. The food service workers are not only pushing paper, they are promoting health and nutrition. There are ways, definitely, that we can eliminate some of the paperwork while maintaining the integrity and the cost effectiveness of the program.

Mr. SKEEN. I will be very much interested in following your progress.

Ms. HAAS. Right, I'll be sure to keep you informed.

Mr. SKEEN. Thank you, Mr. Chairman, and thank you very much for your time.

Mr. DURBIN. Thank you Mr. Skeen. Mr. Thornton.

Mr. THORNTON. Thank you, Mr. Chairman. Welcome, Secretary Haas.

Ms. HAAS. Thank you very much.

WIC NUTRITION EDUCATION

Mr. THORNTON. We appreciate very much your testimony. How do you perceive the line of questioning that Mr. Skeen and the Chairman have raised, with regard to the Outreach Program? The education, the technical assistance, training? Finding ways of visiting in homes? Because I am deeply concerned with prenatal care of children. And concerned about, low birth weight. About children born with fetal alcohol syndrome. Children, first born children whose parents have never borne a child before and who may not be familiar with available resources. What are you doing to address that?

Ms. HAAS. We have developed increasing amounts of material to distribute, certain brochures that we provide at each clinic about problems related to alcohol and drugs and related issues. I think that each clinic can be that kind of focal point for information and for support. I believe that is also very empowering for the individual since many of those young mothers who come into our clinics are teenagers themselves—

Mr. THORNTON. Yes, they are.

Ms. HAAS. We are providing them with the skills to carry on—

Mr. THORNTON. And they do come in during their pregnancy for the first child, is that correct?

Ms. HAAS. Right. And then the clinic is basically, as we say, a gateway to other health services. So we can be the focal point that provides that kind of education, that kind of building of self-esteem, both as a way of taking care of their child, and also themselves, which is very important.

INTER-AGENCY NUTRITION RESEARCH

Mr. THORNTON. I am familiar with the tripartite basis of effective dissemination of knowledge. Education, teaching, but also research.

Ms. HAAS. Right.

Mr. THORNTON. There is not much in your program for research, is there?

Ms. HAAS. We do have \$20 million in the FNS budget for our Office of Analysis and Evaluation, which is our research arm.

Mr. THORNTON. Yes, but now, I heard you describe that as being in part, administrative. Are you looking at health issues, as well?

Ms. HAAS. No. We do not deal with the actual health research, and I think that should be an integral part.

I think that one of the things that we have to look at is that we can not do nutrition education or work on these health issues in isolation. When we were doing our school lunch hearings, we worked very closely with the Department of Education as well as the Department of Health And Human Services. And we've got to take that kind of integrated approach. We need to work closely with NIH and other agencies to do that.

Mr. THORNTON. That gets to a theme that I am pursuing with the Food And Drug Administration when they have appeared before this subcommittee, with the Environmental Protection Agency when it appears before another subcommittee on which I serve. With the National Science Foundation and the Office of Science and Technology Policy, which appear before subcommittees on

which I serve. With the Secretary and others, I have been asking why some efforts are not being made to cross-patch between the different arms of government, progress in research and knowledge so that you may disseminate on the basis of the most advanced information available.

Ms. HAAS. I could not agree with you more. As we make nutrition more of a priority in the Department of Agriculture and through the Secretary's reorganization efforts, we have an opportunity to do just that. We know that nutrition really is a bridge between food and agriculture and health, and we have got to keep that bridge open and we have got to really have everyone walk the bridge, if you will. I think that that is a very important concept, but in reality we have got to do more of that, and we intend to.

Mr. THORNTON. We can do better than continue to do this in a fragmented way with NIH doing their studies in isolation from the human needs that you can identify—the Food and Drug Administration concentrating on food safety but not on nutritional values of food——

Ms. HAAS. Right.

Mr. THORNTON [continuing]. With no one really looking at the effects of food in the early stages of pregnancy on the developing fetus and upon the baby that is born at a children's hospital. Why can't we cut through the red tape and do some coordinating?

Ms. HAAS. Well, we have been trying. Let me share with you another story about that, too, with school meals. I knew that if we were going to achieve any of our objectives, we had to work with the Department of Education. When I went to the Department of Education and met with the Assistant Secretary, Tom Pazant, they said that this was the first time that anyone from the Department of Agriculture had ever come over to the Department of Education——

Mr. THORNTON. Wonderful.

Ms. HAAS [continuing]. To talk about nutrition. They then—it seems so automatic—they then presided with me at the hearings, as did HHS. When we began this process, I asked Deputy Assistant Secretary Mike McGinnis to come over and brief the nutrition service staff on the Dietary Guidelines and on his background in health and the medical basis of the Dietary Guidelines. So I believe that we cannot accomplish our goals unless we have that kind of cooperation.

Mr. THORNTON. What can we do to help? Will you work with me and with my staff and the committee staff to identify ways that we can encourage this kind of cooperation?

Ms. HAAS. I would be delighted to. Thank you.

Mr. THORNTON. Thank you very much. Mr. Chairman, that concludes my questioning. I have to go to the floor to vote on something that I have not read—the journal, the report of yesterday's activities—so I have got to get over there and run through that real quickly in order to find out how I am going to vote.

Mr. DURBIN. I am trusting that you will advise all of us. [Laughter.]

Mr. Peterson.

PAPERWORK REDUCTION IN THE SCHOOL LUNCH PROGRAM

Mr. PETERSON. Thank you, Mr. Chairman. I think this seat is prone to get the votes. You notice how my turn gets preempted by a call for vote time and time again? I will be very, very quick.

I am pleased, Madam Secretary, to hear of some creativity in your chair. And that is one of the concerns I have, particularly with the School Lunch Program. I do not see the level of creativity there that could be. There are just so many things that could happen to make this whole process so much easier.

One little case in point is, and maybe not so little, but just going through the statistical base, you serve about 248,000 reduced price meals. In the overall, that is not very many. And, yet it is a huge part of the paperwork nightmare that is associated with the school personnel that are out there. It is a huge complaint as well with those folks. They do more paperwork than they do any kind of nutritional processing.

And, then another issue is the application for the meal. It is two pages of instructions and a couple pages of application, one for each child. It is not for a family, it is one for each child. And, when I talked to your staff they said it was really as simple as they could get it. And it just flashed in my mind that the IRS people think the 1040 is simple, also. [Laughter.]

This is not simple. You are dealing with people who are not terribly sophisticated in the first place. There is a whole industry that assists those people with the IRS, yet we submit to them a request for an application here that is far too complicated. I can assure you I could sit down, very quickly, and draft a form that could be answered in about 30 seconds. It has to be looked at. This paperwork is just a nightmare.

Ms. HAAS. We have not come out with our proposals at this point, but we regard the paperwork reduction and streamlining the administration as central to any effort to reform our School Lunch Program.

There is one very important opportunity to reduce the paperwork for the vast majority of children who are enrolled in a pre-school program and live in households that are food stamps or AFDC families.

Mr. PETERSON. Right.

Ms. HAAS. You wouldn't even need an application through a process of direct certification for those that are participating in food stamps or AFDC, and already—you would reduce a significant amount of the paperwork. That is something that we believe we have as a pilot, something we want to expand, and it is also part of our whole overall effort.

I think that taking a look at applications is something that I know the Administrator is very concerned about, not just for our School Lunch Program, but for food stamps. Secretary Espy and I went to West Virginia and applied for food stamps. It took us both over an hour to fill out that application. And I think it's very important for us to look at all of the entry points into our programs as opportunities for change.

Mr. LUDWIG. Any time you talk to school lunch people, the first thing they talk about is paperwork reduction, so we are very ac-

tively looking at that. Currently I think there are 47 states that are using some type of direct certification process through the welfare office. In those areas where they are not doing it, it's not mandated on the local welfare offices. They have to do it in just a spirit of cooperation. Most of them do it, but some of them do not. That is a significant reduction in applications you are talking about, because those people who are eligible for AFDC are automatically eligible for the School Lunch Program. So we are encouraging direct certification to see if we can get those welfare commissioners who are not participating involved. It's nothing more than a disk, a tape that they share.

APPLYING EBT IN THE SCHOOL LUNCH PROGRAM

Mr. PETERSON. Well, I think you have an opportunity here of using a system similar to the EBT. A standardized card that you receive when you get your food stamp card. Each kid gets their little card that looks exactly like what everyone else has in a national scheme. You take away the stigma from the kid walking through the line, as well.

Of course, you are talking about having some standardized systems, but if there was ever an opportunity to do it, it is now. By using the EBT program to standardize both food stamp and school lunch applications, because those kids will obviously qualify, we could kill two birds with one stone.

Mr. LUDWIG. That is being tried in some schools right now. The technology is really not even EBT, it's not quite as sophisticated, but that concept is operating today. It is more like a smart cash register than anything else, and there are some school districts that are trying out that technology today.

Mr. PETERSON. We need to simplify the program and make it work.

Ms. HAAS. I think that is why I mentioned earlier that one of our principles in changing the program is flexibility, because it can't be all national since it's very different at the local level.

Mr. DURBIN. We're down to five minutes on this rollcall vote. I sent Mr. Pastor over early so he can come back and I hope soon.

Mr. PETERSON. He got lost in the Rayburn Building.

Mr. DURBIN. He might have. We have to go vote. He will be here to ask a few questions and we'll be right back. So, stand at ease for a moment.

[Recess.]

OUTREACH IN THE WIC PROGRAM

Mr. PASTOR. I want to pick up where we left off and to make some comments. Before I came to Congress, I was in county government, where we operated the WIC program. At one time, because it was the right thing to do, we offered to any pregnant woman, regardless of her income, free prenatal services, which included the whole gamut of services. And, much to our surprise, we found that many women would not take advantage of it.

Transportation was a big problem. Cultural attitudes interfered also. We found that in many cases, for various reasons, individuals just would not take advantage of the services. We did find out that

if somehow we were able to counsel prospective clients, they would come in and take advantage of these valuable services.

I have seen a health promotion and prevention program which has worked well in many Spanish-speaking areas of Arizona. It has also been used in Puerto Rico effectively. Health promoters, who are also members of our communities, do outreach work and encourage women to take advantage of health services available to them. Because these women are respected members of their communities, they are able to counsel and encourage others to practice preventive health care. I think that is what Mr. Skeen was referring to.

Ms. HAAS. And certainly the outreach at the local level is a priority.

At one of our regional hunger forums with Congressman de la Garza in Texas, there were also representatives from some of those programs in his district that have very impressive results. I think we need to look at more ways of just delivering services that meet those needs of people who beforehand were not getting our services.

So outreach is very, very important.

Mr. PASTOR. I think there are some barriers out there that just keep people from using services. Transportation is a big barrier.

Ms. HAAS. Especially in rural counties——

Mr. PASTOR. Rural counties——

Ms. HAAS [continuing]. Right.

Mr. PASTOR. Rural counties are about the worst.

Mr. LUDWIG. One of the things we found that is statistically true across all our programs is that out of an eligible population, normally about 85 percent actually participate. So our outreach is normally towards that other 15 percent. But statistically, that holds with most of our programs. Food stamps is a little bit lower.

CASHOUT IN THE FOOD STAMP PROGRAM

Mr. PASTOR. Since you mention food stamps, let me say I am an advocate of cash. It works in Puerto Rico. Will it work on the mainland?

I hear so much about how people are learning how to beat the system. I think, therefore, why do we not just send a check. We do not have to, you know, go through that infrastructure development. All you have to do is make food stamp recipients eligible and send them a check.

Ms. HAAS. Well, you move away from the purposes of the Food Stamp Act, which really is assuring a nutritiously adequate diet. And when you move to cash, you move to declining food purchases, because the cash is never going to be designated for food. Instead, it's spent on anything from paper towels to——

Mr. PASTOR. Well, I have been told that in Puerto Rico the majority of people who get cash buy food and end up properly using it to feed themselves.

Ms. HAAS. We have data that shows that, not so much the Puerto Rican program, but in cashout pilots, food purchases have declined—I think up to 20 percent.

And that gives us great concern. Also, in our vision for a new Food Stamp Program, with the delivery of service with EBT, you're

changing something that's very important to the client, and that is promoting dignity.

Today with food stamp coupons, many of the food stamp recipients are embarrassed. It is a stigma. But when you have a card, as everybody does when they go into a supermarket today—many people have the bank card—you have dignity.

Also, what's been missing from our Food Stamp Program is any kind of nutrition education as an integral part, the way we have for WIC. Even though we provide the food benefit, we have not provided the education to help recipients make those wise food choices.

So in reinventing the Food Stamp Program, we can address some of those issues while assuring that the recipients are going to get access to nutritious foods. You don't have that assurance when you go to cashing out.

ELECTRONIC BENEFIT TRANSFER

Mr. PASTOR. Well, will not the card carry a stigma because, once we see it, we are going to know who is a food stamp recipient? So how much of the stigma are you removing?

Ms. HAAS. A growing number of supermarkets today, and I would say in the next five years it will be probably most, have a point of sale machine or an ATM machine. More and more people are using their card or the supermarket card, so you will not be able to distinguish.

Plus the fact that the EBT card will be for all programs, not just for food stamps. So that there will be access for social security benefits and for other programs as well, to access any federally-funded benefit programs.

This is an example of that card, the Independence card from Maryland, with the magnetic stripe on the back. But it looks just like any other ATM bank card, which we all carry in our wallets.

Mr. PASTOR. Soon maybe one of the things we will have is the national health card, so we will all be——

Ms. HAAS. Exactly.

Mr. PASTOR [continuing]. Equal.

Ms. HAAS. It's a parallel card to that, exactly.

Mr. PASTOR. It will do everything.

Ms. HAAS. It's a card of the times.

THE EMERGENCY FOOD ASSISTANCE PROGRAM

Mr. PASTOR. Maybe all of us will be using the health card.

I have been getting petitions from my constituents. In fact, the latest one came in from a senior citizens group in Tucson. And they are saying, please do not do anything to cut back on TEFAP.

I realized the administration is proposing to retain funding for the administration of TEFAP, and to support the infrastructure of commodity donation programs

We now have an infrastructure dependent on the TEFAP commodities. Yet, the administration is proposing to zero-out the funding for the purchase of bonus commodities.

How are we going to replace it?

Ms. HAAS. Well——

Mr. PASTOR. I mean, not everybody gets food stamps.

Ms. HAAS. Going back to Mr. Skeen's earlier comment about our 15 food assistance programs. It's really a question of priorities, but maintaining what's essential.

And by keeping the administrative funding, keeping the pipeline open, we really can ensure that those food banks will have that pipeline now for non-TEFAP commodities, which oftentimes represents about 90 percent of the food available in food banks. So we're really talking about the majority of the food.

Also, we have an increase in the soup kitchen and food bank program of \$10 million, so that we did increase that. And I think that that's very important.

The TEFAP program was started as a temporary emergency food assistance program.

Mr. PASTOR. I agree with you, but now there is a whole new infrastructure out there that relies on that.

Ms. HAAS. That's why we kept open that pipeline, to make sure that that infrastructure can be used.

And also, we will be providing at the same time bonus commodities, which are dependent on surplus and dependent on the supply situation of agriculture.

So we still are providing that network and, providing at the same time, the increase in the Mickey Leland Hunger Relief Act to eliminate the barriers that had existed for some people who were not participating in the Food Stamp Program. They can now participate and get those benefits.

With the combination of the growth in the Food Stamp Program, together with the increase that we have in soup kitchens and food banks, and keeping the TEFAP pipeline open, we believe that we will be able to answer the needs that exist in the community.

REINVENTING FOOD ASSISTANCE PROGRAMS

Mr. PASTOR. I am impressed by the work that you have done in feeding programs, food programs, et cetera. And one of the concerns that I have is that, as you have mentioned, some laws we have in place were adopted 30 to 60 years ago. But, we have a different population now. It is older, for one.

Could you describe to me what you would think would be an ideal food assistance program? We have the farm bill coming up in 1995 and I think it will provide an opportunity for us to examine and overhaul these important food programs.

And you admitted, and I agree with you, there is still hunger in this country.

Ms. HAAS. And it's very unfortunate.

Mr. PASTOR. Is there a better way of doing things and making sure that people who are in this country do not go hungry, regardless of their age or their status?

Ms. HAAS. I think that there's an opportunity for us to emphasize two areas.

One is the access question. Are we doing all that we can to provide that access? And that does include providing information about the programs, providing the outreach in the programs, and reducing the barriers. Because as these programs have grown up, we've put in place a great many barriers.

Also, with welfare reform, I think we recognize that it's so important to make work pay, to make sure that our programs are not giving disincentives to those who are working and who need day care, for example, or child care.

The second part is also the educational opportunity. How we can integrate, as I mentioned earlier, health and nutrition into the Food Stamp Program. So we have talked about various ways of reinventing the Food Stamp Program; also reinventing how we administer it. What do we do about the large numbers of errors, and how do we deal with the quality control system?

I think that there is a real opportunity with the reauthorization of food stamps to look at these issues.

Mr. PASTOR. What should be our combination of programs? I would think you would be the best person to say, I have seen the programs that we have in place. We know what the objective is. We have a chance to change things and this is what I propose we do. And, so, I am trying to get a feel from you about what you would recommend to us.

Ms. HAAS. Well, we've dramatically embarked on the road to change our school meals programs so that they promote the health of children.

Mr. PASTOR. Well, on that point, is ketchup in or out?

Ms. HAAS. Ketchup is not a vegetable.

Mr. PASTOR. Oh, okay.

Ms. HAAS. I will tell you unequivocally, there is no question. And we like broccoli, too, and carrots.

But I think that we're trying to bring the health objectives and the nutrition objectives into our school meals program. Each of the programs has an opportunity for change and for building on the purposes for which they exist.

Maybe our administrator would like to add to that.

Mr. LUDWIG. The primary program that's a defense against hunger is our Food Stamp Program. As I mentioned a minute ago, approximately 85 percent of the eligible people within a target population utilize any program.

Food stamps is lower than that. Approximately 60 or 65 percent of the population that's eligible actually participate in food stamps. So we are trying to look at ways to do outreach to those people, and bring them into the Food Stamp Program.

Transportation problems are a cost, yes, but there are factors other than transportation, stigma being one. That's one reason we're trying to push the EBT cards, to do away with some of the stigma.

Our primary force against hunger is the Food Stamp Program. Many of these other programs, the NPE program and the TEFAP program, are secondary programs to try to catch those people who fall through the cracks of the Food Stamp Program. We are constantly pursuing modifications in the Food Stamp Program and I believe that the Mickey Leland Act puts regulations in place that allow more people to come into the program.

ELIMINATING STIGMA IN THE SCHOOL LUNCH PROGRAM

Mr. PASTOR. Let's talk about stigma, in the School Lunch Program and the School Breakfast Program and all the programs we

have in schools. As students become older, they become aware of the stigma that free or subsidized lunches carry.

Yet, in today's society, you may have children who are going to school whose parents' income is just a little too high to qualify for some of these subsidies.

Knowing that our objective is to make sure that all our children are fed and have a nutritious breakfast and lunch and other snacks, and knowing that there's a stigma associated with these programs, would the objective of free lunch or free breakfast for any and all students be a good objective for us?

Ms. HAAS. Let me say that it's a question, really, of budgetary priorities, again, and budgetary resources that are available. The estimates that I have seen for a universal free lunch would be somewhere over \$7 billion in addition to the money we've estimated in our budget request. And some of that money, certainly, would be to subsidize the lunches of children whose families were earning upper incomes.

If our goal is to reduce the stigma for children who need that lunch and are poor, there may be other ways that we can achieve that goal.

One of the things we've talked about earlier is direct certification, so that if a child comes from a family that is a food stamp household or an AFDC household, there would be no further paperwork requirement. Then that child would not necessarily have the same stigma.

Also, we've been piloting the use of census data in some schools that are predominantly low income, where 70 or 80 percent of the children come from low income families, rather than applying the regular reimbursable definitions.

So there are different alternatives for reducing the stigma without the added cost of \$7 billion at a time when we're all facing deficit reduction options.

Mr. PASTOR. Should we look at the reality of today, that today we have many women who are single parents, who are working in jobs that do not pay that well, but pay enough to disqualify them from some of these programs, including the School Lunch Program?

INCREASING FOOD ASSISTANCE PROGRAM PARTICIPATION

Can we look at a different standard for eligibility?

Ms. HAAS. Certainly the child nutrition reauthorization process opens up all those issues. And there certainly is an opportunity in the Mickey Leland Hunger Relief Act; we look at why people are falling through the cracks. For example, there was a vehicle asset test that many people in rural poor counties could not meet. So we were able to change that somewhat to help more rural poor participate in the Food Stamp Program. If there is a problem that's not being met, this is an opportunity to address it.

Mr. PASTOR. Let me ask, do you think there is a problem?

Ms. HAAS. I am sure that there are poor children who can benefit from the School Lunch Program, who may not be participating today. And we have to find a way of reaching those children.

Mr. PASTOR. That's what I'm trying to do. I need your recommendations.

Ms. HAAS. Well, I mentioned to you that direct certification is one. I think that there are various ideas that we have been using to try and reach them; and also I think some of the children are not participating in the School Lunch Program today because their parents believe that it's not healthy enough.

We need to improve people's confidence, because we only have 54 percent of the children participating in our School Lunch Program. I think we have a wonderful opportunity now to promote the health of the program and the confidence in the program, and how good it is for children.

AMERICA THE BEAUTIFUL FUND

Mr. PASTOR. One last question, Mr. Chairman. This deals with America the Beautiful Fund. This program provides seeds for people who want to grow their own food and lower food costs. How would this idea fit existing programs? Do you support the donation of seeds for vegetable gardens?

Ms. HAAS. Yes, in fact, I'd like to see it in some schoolyards. We heard at our hearings some wonderful ideas for edible landscapes at schools where they had gardens. Then the children had the opportunity to harvest their own foods, which they could use for lunch. They learned about the nutrition and cost of foods. So it really is from the seed all the way to their lunch.

Mr. PASTOR. Well, I think we're going to get to the folks as quickly as we can.

Mr. PASTOR. Would you provide for the record a description and evaluation of how the various food programs administered by FNS help mitigate hunger in this country. More specifically, I am interested in seeing which groups, or pockets of hunger, are being helped by each of the programs administered by FNS.

Also, I would like to see how the Department of Agriculture assesses the effectiveness of these programs. For example, what process or approach do you follow to examine which groups are not receiving assistance through our food programs? Likewise, do you evaluate the extent to which our food programs overlap or fail to ensure that the intended recipients or services are indeed receiving this assistance?

Mr. LUDWIG. The mission of the Food and Nutrition Service (FNS) is to alleviate hunger and safeguard the health and well-being of the Nation through the administration of nutrition education and domestic food assistance programs. Taken together, the Nation's food programs form a network of basic assistance to meet the needs of most low-income families and individuals and supplemental assistance to meet the special needs of some, particularly pregnant women, infants, children, and elderly. In recognition of the diversity of low-income Americans and their needs, food programs deliver benefits in a variety of forms (coupons, commodities, cash reimbursement), through a variety of institutions (schools, food banks/soup kitchens, welfare offices), and to a variety of target groups. I will provide additional information for the record.

[The information follows:]

The 15 domestic food assistance programs are the:

Food Stamp Program (FSP): FSP is the cornerstone of the USDA food assistance programs. FSP issues benefits to eligible low-income households to enable them to obtain a better diet by increasing their food purchasing power.

Nutrition Assistance Program (NAP): NAP provides grant funds to the Commonwealth of Puerto Rico to operate a food assistance program tailored to the needs of its low-income citizens provided the program assures assistance for the most needy persons in the jurisdiction.

National School Lunch Program (NSLP): NSLP provides cash and commodities to nonprofit food services in schools and residential child care institutions. Low-income students may qualify to receive their lunches free or at a reduced price.

School Breakfast Program (SBP): SBP provides cash and commodity foods to nonprofit food services in secondary schools and residential child care institutions. Low-income children may qualify to receive breakfasts free or at a reduced price.

Child and Adult Care Food Program (CACFP): CACFP provides cash and commodity assistance to non-residential child and adult day care centers and, through sponsor organizations, to family and group day care homes for children.

Summer Food Service Program (SFSP): SFSP is designed to provide food service to children in needy areas—where at least half the children come from families with incomes below 185 percent of poverty—during school vacation periods. All meals are served free, but reimbursements are limited to lunch and either breakfast or a snack.

Special Milk Program (SMP): SMP provides funding for milk service in some kindergartens, as well as in schools, nonprofit child care centers and camps which have no other Federally-assisted programs. Milk is provided to children either free or at a low cost depending on their family income level.

Special Supplemental Food Program for Women, Infants, and Children (WIC): WIC's goal is to improve the health of pregnant, breastfeeding, and non-breastfeeding postpartum women, and infants and children up to five years old. This is achieved by providing supplemental foods, nutrition education, and access to health services.

WIC Farmers Market Nutrition Program (FMNP): FMNP provide WIC participants, or persons on a waiting list for WIC services, with coupons that can be used to purchase fresh fruits and vegetables at authorized farmers markets. The coupons are in addition to the recipient's regular WIC food benefit.

Commodity Supplemental Food Program (CSFP): A direct food distribution program with a target population similar to WIC, CSFP also serves the elderly. Recipients may not participate in both WIC and CSFP. As in WIC, food packages are tailored to the nutritional needs of participants.

Food Distribution Program on Indian Reservations (FDPIR): FDPIR provides commodity foods to Native American families who live on or near Indian reservation who choose not to participate in the Food Stamp Program.

Nutrition Program for the Elderly (NPE): NPE provides cash and commodity foods to States for senior citizens. Food is served in senior citizen centers or delivered by meals-on-wheels programs.

Commodity Distribution to Food Banks and Soup Kitchens: FNS provides commodities from USDA surplus stocks to nonprofit, charitable institution that serve meals to needy persons regularly. These include homes for the elderly, hospitals, soup kitchens, food banks, meals-on-wheels programs, summer camps, and orphanages that do not participate in any Federal children nutrition program.

Emergency Food Assistance Program (TEFAP): TEFAP helps States to relieve situations of hunger and distress by making available surplus foods from USDA farm support program inventories.

Nutrition Education and Training Programs (NET): NET provides funds for training school food service personnel in food service management, instructing teachers in nutrition education, and teaching children about the relationship of nutrition to health in order to assist them in making wise food choices.

On any given day, the Nation's food assistance programs touch the lives of over 40 million (or one in every six) Americans; food stamps reach over 27 million needy Americans; WIC serves two out of every five babies born in the United States; and school meal programs reach more than 25 million children. Moreover, participation in these programs has been shown to be linked to desirable outcomes (line increased and more nutritious food consumption, better birth outcomes).

FNS has an ambitious research agenda to support the agency's policy makers with current policy research on issues related to food assistance programs. Our research includes:

Evaluations of welfare reform, coordination, and simplification projects; evaluations of the effectiveness of FNS programs; analyses of participation in FNS programs, including participation rates, trends in rates over time, and other participa-

tion-related issues; research on nutrition education and monitoring to determine if FNS programs meet the nutritional needs of the populations they are designed to serve; and research on program operations and integrity to provide information and technical assistance to State agencies on how they can reduce costs and increase effectiveness and inform Federal policy and regulatory decision-making.

Mr. PASTOR. The school lunch program has the unfortunate consequence of stigmatizing some of the students who benefit through the free lunch program. You indicated in your testimony that removing the application and certification process from the schools and placing it within other social services offices would help eliminate this type of stigmatization. Still, I understand that much of the problem surfaces within the school lunch facilities or cafeterias, where students who qualify for a fully-subsidized meal are indentified by the individual collecting payments at the beginning of food lines. Would you be able to develop some recommendations to help prevent this "de facto" or unintended identification of program beneficiaries?

Mr. LUDWIG. Both the National School Lunch Act and the program regulations expressly prohibit the overt identification of children who are eligible for free and reduced price meals. This means the school may not publish, post or otherwise announce the names of these children or use special tickets or tokens to identify them. Since conditions vary greatly from school to school, we do not mandate a specific system for all schools to use. Generally, however, if a school makes a "medium of exchange", such as a ticket or token available to all categories of students at the same time and place, we would consider that the school has complied with this obligation. The exception would be if tickets had obvious identifying characteristics such as color codes or the name of the category stamped on them. In these cases where a child's status could be readily apparent to a casual observer, the State agency would require the school to take corrective action.

I must emphasize that it is essential for the school food service to be able to identify the meal at the point of service so that the proper level of reimbursement can be claimed. To this end, the medium must have some manner of identification that would not be obvious to a casual observer. For instance, a school could use a numbering system known only to food service personnel. One system which is gaining in popularity is computer based and involves the use of scanners to read coded identification cards.

Mr. PASTOR. Thank you very much.

Ms. HAAS. Okay.

Mr. DURBIN. One of the hazards of voting is that you run into colleagues, and one of them I ran into is Patsy Mink. [Laughter.]

HAWAIIAN PINEAPPLE—BUY AMERICAN PROVISION

I told her we brought up her issue about Hawaiian pineapple and she said, "what did they say?" and I said, "I'm not sure, but I'm going back," and so now I have to ask you again, now that I've made my case here, is there any doubt in your mind that school lunch programs are required to buy American Hawaiian pineapple products under the Buy American provisions?

Mr. BRALEY. Mr. Chairman, the local purchases, and again, I'll have to check this for the record, are not governed by the Buy

American requirements; there's not an enforcement mechanism. I'll have to double check because I could be wrong. The figures that Mr. Dewhurst has with him indicate that we bought about \$5 million worth of U.S. grown pineapple in 1992. It doesn't appear that we bought any last year, but I believe we have some programs in effect this year.

As you know, the Section 32 program works based on the market conditions. If they made a case that relief is needed, we certainly through our programs can find an appropriate outlet for canned pineapple, as we have in the past.

Mr. DURBIN. Here's what the law says under Buy American when you're purchasing food products with Federal funds, recipient agencies shall, whenever possible, purchase only food products produced in the United States, and then they set out some exceptions. Now wouldn't recipient agencies include school districts receiving Federal funds?

Mr. BRALEY. Yes, I think the majority of the foods they would buy would be of domestic origin, just based on what's in the marketplace. I think the situation would arise that they have locally generated funds, either from the school district or from the State, or even from children's payments, and you could argue that the food that I bought that was not of domestic origin, was paid for with local funds rather than Federal funds. But I'm going to have to do a little more research on this for the record.

Mr. DURBIN. Well, I hope you will, and then we can both meet with Congresswoman Mink.

[Additional information follows:]

Section 3(h) of the Commodity Distribution Reform Act and WIC Amendments of 1987 (P.L. 100-237) requires that recipient agencies purchase, whenever possible, only food products that are produced in the United States. Exceptions to this requirement are permitted when recipients have unusual or ethnic preferences in food products; and for such other circumstances as the Secretary considers appropriate. The legislation exempts those recipient agencies located in Alaska, Hawaii, Guam, American Samoa, Puerto Rico, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands from the buy American requirement because, given their locations, it would not be economically or logistically feasible to restrict their purchases to American-produced foods.

Under the authority granted the Secretary in the legislation, current Federal regulations exempt recipient agencies from the buy American requirement in instances when: a desired product is not produced or manufactured in the United States in sufficient and reasonably available quantities of a satisfactory quality; or the cost of a United States produced food product is significantly higher than the foreign produced counterpart. No further guidance has been issued to supplement the regulations.

WIC NO SMOKING REGULATION

Mr. DURBIN. Mr. Ludwig, what happened with our recommendations on smoking regulations in WIC clinics? You've talked a lot about the educational aspect, but are the WIC clinics smoke-free across America now?

Mr. LUDWIG. Yes, sir. We have a regulation that no administrative funds can go to any WIC agency that does not have a no smoking policy. We're also in the process of purchasing a number of materials from the March of Dimes concerning the ill effects of second-hand smoke to individuals.

Mr. DURBIN. What kind of problems have you run into with this smoke-free policy?

Mr. LUDWIG. To my knowledge, no significant problems.

Mr. DURBIN. Okay, I wanted to put that on the record, because some other folks don't believe it.

Mr. LUDWIG. Not to my knowledge.

Mr. DURBIN. Thank you.

Mr. SKEEN. They will believe.

Mr. DURBIN. If there is anything that you can share with us that points to a better way to implement it, I would appreciate it.

Mr. LUDWIG. We'll look into that.

U.S. NUTRITION POLICY

Mr. DURBIN. I want to go back to questions that have been asked. My last question to you, Ms. Haas, relates to the fact that I've asked staff recently to maybe do the impossible. I've asked for a chart on all of the food nutrition programs at USDA to try to figure out when we step in and try to feed people, which we do a lot of in different stages in life. Mr. Skeen made the point earlier that it's hard to imagine that a person who is hungry doesn't have some available food in this country today.

There's also a bigger question as to whether or not we have a consistent nutritional policy across all feeding programs in terms of what we are trying to achieve. We know for example, the School Lunch program, as mentioned earlier, does not meet dietary guidelines. Are we moving towards a consistent nutrition policy, as you see it?

Ms. HAAS. Yes, I think we're doing at the Department of Agriculture what some people have characterized as moving from the nutritional neglect stage to taking responsibility, that what we need to do is real nutrition assessment. We hope to bring together nutritional leaders at the end of May to talk about new visions in nutrition within the Department of Agriculture, to make nutrition a real priority.

As we learn about the health consequences of poor diet, and how very much nutrition is a part of prevention, and how we can cut health care costs like we're doing with smoking problems, we need a consistent policy. With WIC, I've been amazed at the success of building nutrition education into the infrastructure of the program, and the kinds of health outcomes that we get. Yet we don't have that kind of infrastructure in some of our other programs, like food stamps, or even school meals.

So we are trying to do just that. It's an enormous task with programs that reach one in six Americans, and we're spending \$40 billion. I believe, as I said earlier, we have a national health responsibility as well as a food responsibility.

Mr. DURBIN. Thank you. Mr. Skeen, any followup questions?

Mr. SKEEN. No questions, Mr. Chairman. In that same vein, I think too that we fall prey to a lot of selective advertising about nutrition. For instance, in some recent news reports, if you're carrying a bag full of garlic pills, you're really missing out on your next heart attack, and all these kinds of things. And there ought to be some way that we can focus this better, and you're in the best position of all for doing it.

Ms. HAAS. Absolutely.

Mr. SKEEN. And to cut through some of this business of just making it a popular daytime sport to come up with the next nutritional fad.

Ms. HAAS. Right, and we do have that kind of expert. Every five years the expert committee on the Dietary Guidelines meets. The guidelines reflect what is the scientific consensus. I don't believe that we can move in any direction unless it has a solid scientific basis, and we do have the mechanisms to do that.

But then we have to communicate it. You just talked about what you hear on the radio. I heard on the radio something very encouraging in California, and this has to do with smoking reduction, that when they had their major—

Mr. SKEEN. This makes our Chairman's whole day.

Ms. HAAS. This is amazing and I think it is a very important model for nutrition education. They found that within the last year when they did this major educational campaign using advertising, using TV, they were able to reduce smoking by 28 percent. The least effective was print material inside the doctor's office.

Well, I believe, too, we've got to change nutrition education from being something we do with paper brochures to something we do with video and advertising. That's why we have in our budget a small amount of focused money that we are proposing; \$20 million for nutrition education, training, and technical assistance.

We've got to communicate where the other messages in food advertising are effectively communicated—all across our TVs. We've got to complement and really give an effective message on nutrition education where kids are, where families are, and that's through TV as well as through the paper brochure.

Mr. SKEEN. Well, if we can get rid of the yearbook, I think that we can probably do a better job of it.

Ms. HAAS. It's gone.

Mr. SKEEN. I would like to see sometime in my lifetime that a federal agency of the importance of the Department of Agriculture could come out and say that this is what you need to know about nutrition, and you really have an acceptance and believability, credibility, across the whole spectrum, because you are a front line agency.

Ms. HAAS. To do that, Congressman Skeen, we need—

Mr. SKEEN. You need money.

Ms. HAAS. No, not only money, we need the institutional structure within USDA to be able to do that, so that we can deliver the services, not only food assistance to those who need it, but nutrition research and education, and then we are prepared to move into the next century to promote the health of all Americans.

Mr. SKEEN. Well, Madam Secretary, with all the folks that we're funding, and the agency over there who is supposed to be doing public relations work, somewhere along that line we ought to be doing a better job. But I think you're exactly right, and you've got the right approach. And I can say we'd like to be a part of that team with you.

Ms. HAAS. Thank you.

Mr. DURBIN. Thanks, Mr. Skeen. Ms. Haas, one of the things that came out of that California study was a reduction in the number of smokers, but the lack of success in teenagers. It's a tougher

sell. They think they're indestructible and can quit smoking. I think the same thing may be true on nutritional information. As you and Mr. Ludwig said, the nutritional standards which we establish with our youth will last our entire life. My mom always told me to clean my plate, and I've been trying to shed the pounds ever since.

Ms. HAAS. We have a new message.

Mr. DURBIN. Put the right things on your plate. Can I close with one bookkeeping question, which we've asked of each agency, and that is in terms of contract employees. We are going to be asking you to tell us how many contract employees are under your jurisdiction. We understand the Department has a responsibility to reduce overall FTE levels. I have a personal interest in contract employees—how much they cost, and whether or not they're going to be reduced—if the objective is saving the taxpayers dollars. Mr. Ludwig, do you have this information handy?

Mr. LUDWIG. I will submit it for the Record.

[The information follows:]

Since its inception, the Food and Nutrition Service has always relied on the judicious use of contractor employees in those areas where it is not necessary or efficient to maintain in-house expertise. This has proved beneficial to the taxpayer, the business community, and the people served by our programs.

For Fiscal Year 1993, the latest year that we have complete data, the Food and Nutrition Service obligated service contracts totalling \$17,326,000. These contracts were for program evaluation, automated data processing services, program management support, technical assistance, and warehousing and storage. The amount of contractor effort employed on these contracts is estimated at 214.8 work years. We do not anticipate any major change in these service contract levels.

Mr. DURBIN. Some of our colleagues could not be here today, but have questions they would like answered for the Record.

[The questions and responses follow:]

Ms. DELAURO. It is my understanding that it would be easier to combat food stamp fraud, especially fraud on the part of retailers, if the federal government could share information with state and local officials. Twice the house has passed legislation with provisions designed to make this happen. And twice these initiatives have hit snags in the other body. But, suppose for the sake of argument, that this bill, HR 3436, is passed. Will it give you the ability to cut back on the kind of fraud you see on the part of retailers who abuse the program? Is the provision regarding sharing of information strong enough, or do you need more?

RESPONSE. A provision similar to that in H.R. 3436 has been approved by Congress and signed by the President as P.L. 103-225. This change in law will allow the Department to share information provided by the retailers and wholesalers, such as sales and food stamp redemption information, with State and Federal law enforcement and investigative agencies. Before, this information was restricted to persons directly connected with the administration and enforcement of the Food Stamp and WIC Programs. We were very pleased that this legislation passed with the information sharing provision intact, because this will improve the administration of the Food Stamp Program. We would expect that allowing State and Federal agencies to share information provided by retailers will improve the Department's ability to pursue suspected abuses in the program. The Department will be able to more fully investigate illegal activities in the Food Stamp Program which, in turn, should enhance program integrity.

In response to your second question, we do believe a stronger approach might be needed, and we are considering approaches that would strengthen the disclosure provisions in P.L. 103-225. Being able to share Tax Identification Numbers (Social Security Numbers and Employer Identification Numbers) and information in the files of other law enforcement and investigative agencies would enhance the Department's ability to uncover program violations. We do not have this legal authority now. Identification numbers offer much stronger confirmation of identity than do names and addresses alone. However, as you know, legislation involving Social Se-

curity Numbers and Employer Identification Numbers will involve the Congressional Committees with jurisdiction over those matters.

Ms. DELAURO. You have asked for a small (\$28,000) increase for your retailer integrity program, which was last year budgeted at \$1.9 million. As I understand it, this includes funds for 12 investigator staff. How do you determine how many staffers you need for these activities, and is 12 sufficient?

RESPONSE. Special funding for retailer integrity has been used for two purposes. \$1 million is used to assist the FNS Compliance Branch with special efforts against food stamp trafficking. These funds support the salaries and benefits of 12 senior investigators and their related expenses, in addition to other essential equipment and activities related to trafficking. One of these activities involves FNS investigators working closely with United States Attorneys across the country. The investigator develops retailer trafficking cases and the U.S. Attorney then initiates action against the retailer using the False Claims Act (FCA). When criminal prosecution is not an option, using the FCA for civil prosecution against retailers found trafficking has been successful. Since this initiative began in June 1992, negotiated settlements for civil prosecution actions initiated by Assistant U.S. Attorneys total over \$1.4 million.

In addition to the expenses of 12 senior investigators covered by the special funding, the Food Program Administration account funds 37 additional investigators who investigate retailer food stamp fraud. The total budget for the FNS Compliance Branch in Fiscal Year 1993 was almost \$4.1 million. Considering the Agency's priorities, and the additional staff resources devoted to retailer food stamp fraud by the Office of Inspector General, we believe this is an appropriate commitment of available resources to this effort.

The second use of retailer integrity funds is to support the retailer reauthorization process, which updates ownership and sales information of over 200,000 retailers on a biennial cycle. The funding supplements regional and field office efforts for retailer monitoring.

Ms. DELAURO. Is the cost-neutrality rule governing the switch to the EBT program a problem? Does it keep states from going to the EBT? If so, how could it be modified to make the transition easier? What could we (Congress) do to make it more likely that states will come on board?

RESPONSE. Our experience with the Electronic Benefit Transfer (EBT) system shows that once systems are up and operating there is an administrative savings for the Food Stamp Program. For example, we found that the operating costs of issuing food stamp benefits electronically under the EBT system was \$3.07 per case month in New Mexico, compared to the paper coupon cost of \$4.04. In Ramsey County, Minnesota the EBT cost was \$4.38 per casemonth while the paper issuance cost was \$4.53. However, current statutory and regulatory requirements call for States to fold in EBT start-up costs and be cost neutral each year. This represents a challenge for many States, particularly those that operate very inexpensive coupon systems, and the effort that goes into administering this process introduces a new and substantial administrative cost for both States and the United States Department of Agriculture.

There are several alternatives that would help meet this challenge. They include a broader definition of cost-effectiveness that reflects EBT improvements in the quality of service and integrity, applying a more liberal cost-neutrality standard so that States are encouraged to make this investment. The United States Department of Agriculture (USDA) continues to believe that the regular funding scheme which requires States to pay 50 percent of their administrative costs provides the best control for containing State operations costs.

On a related note, States continue to be very concerned about the costly impact of Regulation E. While it will be three years before EBT systems must comply with this rule, some States will have already indicated their intent to defer EBT plans until it is clear how much Federal relief there will be for Regulation E costs.

Ms. DELAURO. Even if all the States switch to the EBT, there will be, as you said in your testimony, new ways to defraud this system. Are you working with Maryland and the cities that are using the EBT to determine how this system might be abused, and what can be done to anticipate and stop attempts to defraud it?

RESPONSE. Yes, but our efforts are not limited to working only with our operational sites. We are aggressively following up on all possible avenues of fraud to ensure that we close them off before fraud occurs (e.g., system design reviews, acceptance testing). We are currently conducting a study on EBT security which is looking closely at the risks posed by EBT systems and will recommend protections that should be utilized.

In the area of trafficking, we have assisted the Office of the Inspector General (OIG) in obtaining transaction history files from the individual Electronic Benefit

Transfer (EBT) projects for their work. Using computer technology, OIG detects patterns of transactions that suggest trafficking. This allows OIG to direct their investigators to stores where the indicators of trafficking are high and conserves their investigative resources.

Another new opportunity for fraud is presented by the extension of "Regulation E" to EBT. The "Regulation E" liability provisions which would limit recipient liabilities for lost or stolen benefits will open up the program to forms of recipient fraud that are not available today. One of the principal purposes of our planned demonstrations of "Regulation E" coverage is to measure the cost of extending such coverage, some of which could be attributed to fraudulent claims.

Ms. DELAURO. You have budgeted \$1.2 million this year for printing food stamps, \$89,000 for shipping them, and another \$1.1 million for redeeming them. Is this money we can expect to save if we move the EBT program?

RESPONSE. Your numbers are the requested increases for printing, shipping, and redeeming food stamps for Fiscal Year 1995. The budgeted amounts for printing, shipping, and redemption are \$73.8 million for Fiscal Year 1994 and are estimated to be \$76.3 million in Fiscal Year 1995. Regarding cost savings, we do expect to save in coupon printing and shipping costs once Electronic Benefit Transfer (EBT) systems are the primary benefit delivery method for the Food Stamp Program. It is uncertain at this time what other EBT costs will be such as a settlement service that meets industry standards. Some of the savings from the reduced need for printing, shipping, and redeeming food coupons may be needed to defray these new EBT costs.

Ms. DELAURO. I read in the USDA budget summary, under the heading of "Food, Nutrition and Consumer Services" that there are plans for closing eight FNS field offices. Aren't these the offices that take care of certifying retailers in the Food Stamp program and overseeing their operations, including undercover visits? If so, what will it do to your efforts and the efforts of the USDA to combat fraud and abuse if these are closed?

RESPONSE. We do not expect the closing of these offices to affect our efforts to combat fraud and abuse. The undercover visits you refer to are conducted by Compliance Branch staff and no compliance office is scheduled to close.

Most of the offices scheduled for closing are one-person offices. The closing will affect only fourteen employees. We anticipate that the staff will be reassigned to other field or regional locations. Likewise, the work previously carried out in these locations will be transferred to other field or regional locations. These eight offices were selected for closure because of the inefficiency of maintaining office facilities for one or two persons; and the work could be accomplished by other larger Agency facilities.

Ms. DELAURO. The USDA request for the Elderly Feeding Program runs counter to reality. Both the number of elderly, and the cost per meal for this program are on the increase. Yet you want to cut funds for the program. In your budget justifications, you state that the meals provided by this program are "the focal point of the nutritional projects for the elderly which have the dual objectives of promoting better health and reducing the isolation of old age." My question is two pronged: How can we achieve these goals if we cut the program, and what is your reasoning for cutting the program back at a time when there is a growing need?

RESPONSE. As you know, United States Department of Agriculture (USDA) provides donated foods or cash in lieu of foods to the Elderly Feeding Program, known as the Nutrition Program for the Elderly (NPE), which is administered by the Department of Health and Human Services' (DHHS) Administration on Aging. The President's budget has proposed that \$141,142,000 be appropriated. While this represents a six percent decrease from the previous year, consideration should be given to the total funding environment in which NPE exists. In Fiscal Year 1994, DHHS was appropriated \$469,474,000 for congregate and home delivered meal service; the USDA appropriation of \$150 million provided funding for cash and commodity assistance for a total of \$619,474,000. Federal appropriations are supplemented by voluntary contributions which program operators solicit from participants. Thus the proposed change can reasonably be expected to constitute an exceedingly small percentage of the total resources available for elderly feeding. Further, we do not anticipate that this reduction will affect the total number or quality of meals served.

The President's budget includes many difficult choices which must be made in this time of severe fiscal constraints. Needs must be prioritized. Unlike almost all forms of food assistance provided by USDA, NPE does not require a means test for the receipt of program benefits. When resources are not sufficient to fully serve all target populations, it becomes increasingly necessary to target them to persons at greatest need.

Ms. DELAURO. I want to commend Ellen Haas for her work on attempting to improve not only the nutritional quality, but the meals themselves, which we serve to our children at school. As you pointed out in your testimony Ms. Haas, eating habits are established by age 12. And as we continue to debate health care, and the need for better preventative care, there is no more cost effective place to start than with people's diets, and no better place to begin teaching good nutrition to our children than at the school lunch table. In your hearings, what were your primary findings regarding the reasons for such high levels of saturated fats and sodium? Is it nutrition education for food service workers, the type of commodities received as part of the school lunch program, or other factors?

RESPONSE. Over 2,350 persons either testified at our public hearings or submitted comments to express their concerns about school meals. Nearly half of these comments were concerned with the level of fat contained in these meals. Many factors influence the foods offered and consumed in the school cafeteria, including the two you suggest. Over 250 commenters recommended that the Department of Agriculture offer a healthier variety of commodities for schools to use in their meal programs, and more than 800 commenters pointed to the need for more nutrition education directed to children and parents as well as food service workers.

We believe that improving school meals requires a comprehensive, integrated approach which promotes the present and future health of our children. As part of this strategy, we have already increased the amount of fresh fruits and vegetables donated to schools, and we are developing and testing a variety of reduced-fat products.

With respect to nutrition education, the Administration's budgetary proposal for Fiscal Year 1995 includes a request for over \$20 million to provide Federal and State technical assistance and training for school food professionals to help implement the Dietary Guidelines as well as nutrition education. It is extremely important that children and their families learn to make wise food choices. We must use new communications technology and electronic resources for more persuasive and far-reaching communications. We have begun to explore joint ventures with our Federal partners—the Department of Education and the Department of Health and Human Services—as well as with interested parties in the private sector, and we expect these efforts will pay off in a better understanding on the part of America's children on what constitutes a healthy diet.

Ms. DELAURO. For students to benefit from your work, Ms. Haas, they have to eat the meals. You have gone a long way to ensure this by consulting many experts on what makes a meal attractive to kids. But one concern I have is that there is a stigma attached to school hot lunches. School lunch program directors from my district tell me that many needy students won't participate in the hot lunch program because they have to purchase and present a coupon for their lunch, and that coupon tags them as being poor. What can be done to avoid this stigma, and increase the participation of children in this program?

RESPONSE. We share your concern that needy children not be discouraged from participating in the School Lunch Program because of a "welfare stigma", and both the law and the Department of Agriculture's regulations prohibit schools from overtly identifying children who receive free or reduced price meals. To comply with this requirement, many schools use a ticket or token system for all children, including those paying the full price. While cashiers must still be able to identify the eligibility category in order to count the meal correctly for reimbursement, schools are prohibited from using obvious identifiers, such as colors or simple number or letter systems, which would enable a casual observer to deduce the child's category.

It is interesting to note that about 80 percent of the children approved for free meals participate on a given day, and many times nonparticipation is due to absenteeism or some other factor unrelated to overt identification. In fact, we believe that people often fail to apply for free or reduced price meals because of complexities in the application process, and this can be a more serious problem. One promising method is direct certification, under which children are certified for free meals based on information obtained directly from food stamp or Aid to Families with Dependent Children (AFDC) officials indicating that the child is a member of a food stamp household or AFDC benefit unit. No further application is needed on behalf of the child. This method is being used in 47 States, and we are actively promoting expansion of its use as a way of reducing paperwork for local operations.

Ms. DELAURO. Ms. Haas, in Connecticut, we have been pleased with the results of the WIC Farmers' Market Coupon Nutrition Program. We now have almost 50,000 WIC participants using coupons to purchase fresh native produce from 155 farmers at our state's 40 farmers' markets. This program has sparked a marked increase in participant's use of fresh fruits and vegetables, improving their nutrition while at the same time developing new markets for small farmers. I understand

that Connecticut's success is mirrored in the other participating states as well. Given this record of success and the growing demand for the program among additional states, does the Administration plan to make the program available nationwide?

RESPONSE. The Administration is very supportive of the Farmers' Market Nutrition Program (FMNP). As you know, the Fiscal Year 1994 appropriation of \$5.5 million for the FMNP represents a substantial increase above the 1993 level of \$3 million. As a result of the increase, 15 State agencies have submitted State Plans for approval to initiate the Program. We plan to fund all of the approved State plans, however, reductions to the amount of funds requested may be necessary in order to bring in all of the States. The 15 State agencies are: California, the Cherokee Nation of Oklahoma, District of Columbia, Indiana, Kentucky, Maine, Minnesota, Missouri, New Hampshire, New Jersey, New Mexico, Ohio, Rhode Island, South Carolina, and West Virginia.

Ms. VUCANOVICH. I do support many of the food programs which fall under your jurisdiction, yet I must tell you, I am concerned that 60% of the entire budget for the U.S. Department of Agriculture has been devoted to nutrition programs. I believe the committee will be taking a hard look at this budget recommendation. With this in mind, I would like to ask you about the Food Stamp program. Earlier this year, the Inspector General testified about the use of their resources to fight Food Stamp fraud and abuse. Please go into more detail about what are you doing within the administration of the food stamp program which would cut down on food stamp fraud and abuse? Could you explain how the electronic benefit system would reduce fraud?

RESPONSE. The States have a number of ways to detect the different varieties of fraud and to catch and punish people who intentionally abuse the Food Stamp Program. These include front-end investigations at the time of the application, computer matches against other databases, hot-lines to receive allegations of fraud, and special units which investigate fraud and street trafficking. In Fiscal Year 1993, States conducted more than 440,000 investigations of suspected recipient fraud.

Recipients who are found to have committed an intentional program violation are disqualified for six months for a first violation, 12 months for a second violation, and permanently for a third violation. Fines up to \$10,000 or imprisonment up to five years can also be applied. In Fiscal Year 1993, more than 74,000 recipients were disqualified for an intentional program violation.

Recipients found to have committed an intentional program violation are required to repay the amount they were not entitled to receive. If the debtor is participating in the program, the monthly allotment is reduced until the overpayment is paid back. For people not participating, the tax intercept program provides States a means to intercept an individual's Federal tax refund to offset against the amount owed the Food Stamp Program if all other collection methods have failed. In Fiscal Year 1993 State agencies collected more than \$37 million in intentional program violation claims using various collection methods.

The Department currently sponsors a number of regional Federal/State work groups which work together to design and share methods for fighting fraud, waste, and abuse. Conferences and newsletters are two of the methods utilized by the Department and these groups to disseminate fraud prevention information and methodologies such as front-end screening and verification. The Department also occasionally brings together representatives from selected urban areas which have the potential for high concentrations of fraud. At these meetings, representatives from areas which have utilized innovative and relatively low-cost methods to combat fraud can share their success stories with their similarly-situated, but not as successful, cohorts. Travel expenses for these meetings are usually fully reimbursed through the Department's State Exchange Program.

The Department is currently drafting proposed regulations to facilitate the administrative disqualification hearing process by making it more cost effective and less burdensome to State agencies.

The Department is implementing a new electronic information system and computer matching program, the Disqualified Recipient Subsystem (DRS), to collect and disseminate information on individuals who have been disqualified from participation in the Food Stamp Program for an intentional program violation. This system helps States to assign the legally-required penalty. States may also use information from DRS to identify and implement disqualification penalties for applicants and current food stamp recipients who should be serving a disqualification imposed in another jurisdiction. There are now records on nearly 200,000 disqualified individuals in the database.

The Department plans to increase the State retention rate effective October 1, 1995 as provided by law for intentional program violation claim collections from the

current 25 percent to 50 percent and inadvertent household error claim collections from 10 percent to 25 percent. These increased funds from the higher retention rates, when they become available, could also be used by State agencies to operate State fraud control programs.

State, local, and Federal governments are working together to take aggressive action to reduce trafficking.

The Food and Nutrition Service (FNS) completed 4,644 food stamp retailer investigations in Fiscal Year 1993; 1,387 of these cases contained sufficient evidence of violations to support retailer disqualification and 841 of these contained evidence of food stamp trafficking.

FNS investigators work closely with the Office of the Inspector General (OIG) and the Department of Justice (Civil Division) to increase the number of civil actions against retailers caught trafficking. Many of the trafficking cases declined for criminal prosecution by OIG have been referred to the Department of Justice for possible civil action under the Federal False Claims Act. Using the False Claims Act to prosecute retailers, when criminal prosecution is not an option, has proven to be successful. In Fiscal Year 1993, 82 settlements were negotiated in 24 districts for a total of nearly \$1.1 million.

The maximum civil money penalty for firms caught trafficking in food coupons or other benefit instruments has been doubled from \$20,000 to \$40,000 per case. Unauthorized people who accept and redeem food stamps may be fined \$1,000 for each violation plus an amount equal to three times the value of the coupons accepted illegally.

FNS has undertaken a major re-authorization initiative of retailers to collect new, updated information including social security and employer identification numbers.

States have been encouraged to pass State food stamp fraud statutes. Most States have such statutes in place. FNS has increased its effort to urge States to engage the cooperation of local law enforcement officials to address blatant trafficking.

Under an electronic benefit transfer (EBT) system, households are issued plastic cards that are similar to credit or debit cards. When a household buys eligible food, a central database is called to check if there are sufficient benefits available to complete the purchase. The value of the purchase is then deducted from the allotment.

EBT helps fight fraud in several ways. First of all, it is a more secure means to issue benefits. Benefits are not as readily lost or stolen since the personal identification number (PIN) is needed to use the benefits. Also, by eliminating the food coupon as a negotiable currency, EBT makes trafficking that would utilize third-parties or middlemen more difficult. Not only must a card exchange hands, but the secret PIN must be exchanged as well. The handling of multiple cards and multiple PINs makes trafficking very awkward for the violators.

Perhaps most importantly, EBT provides the administering agencies with a detailed audit trail on where and when benefits are transacted. We have successfully worked with the States currently operating EBT systems to enable our on-going compliance investigations to be conducted. In fact, the State of Pennsylvania has successfully prosecuted trafficking activity during the past year using the information available from the EBT system as a tool in the investigation. Other EBT sites have also begun to utilize similar data in investigations. These efforts are being refined as we gain additional experience and knowledge.

The Department is encouraging every State to implement an EBT system for providing food stamp benefits to participating households. Currently, seven States are operating EBT systems. Maryland is the first statewide operation. Well over 30 State agencies are currently in some stage of planning and implementing EBT systems.

Ms. VUCANOVICH. You mentioned food stamp error reduction. What portion of your budget was used to reduce errors of issuance last year? You ask for more funding—how would this be used and how is this any different than the funds used last year. Could you provide more detail to justify such funding?

RESPONSE. Efforts to avoid and correct errors have been a priority for FNS and as such, most of the staff involved in administering the program contribute to these efforts in varying degrees. Although funds and staff dedicated to error reduction exclusively have been relatively minimal, our certification policy staff, quality control workers, and staff working on recipient claims play a part in error reduction. As a result, we really cannot provide a specific figure to represent effort on issuance error. This year \$359,000 was provided to the States through the Regional offices for the State Exchange program which facilitates the sharing of best practices and strategies for payment accuracy. Another \$370,000 is currently being used to fund two demonstration grant projects in Chicago and Baltimore testing the effectiveness of specific error reduction procedures. The balance of the Fiscal Year 1993 allocation made possible the addition of one staff person at FNS headquarters to work exclu-

sively on error reduction matters. Also, the seven FNS Regional offices each have one or two staff years dedicated to assisting States in error reduction efforts.

The current FNS budget request of \$1,000,000 and 5 staff years devoted specifically to error reduction reflects the high priority this Administration intends to place on payment accuracy in the Food Stamp Program. If appropriate, \$400,000 (including travel funds) would permit the increase of the headquarters staff by two and would also create three other error reduction specialist positions which would be on-site in States that have the highest certification losses. These experienced staff would provide direct, hands-on technical assistance to State agencies to help them develop effective error reduction strategies based upon the State's specific situation and needs. While the general support to all States must continue, a more focused approach is needed where losses are the highest. They would also assist the Regional offices in making the issue of accurate administration of the Food Stamp Program a priority for legislatures and local government officials. Another \$100,000 would be spent to increase the FNS Regional offices travel budgets to assist all States in need of specific direction. An additional \$250,000 would be spent to increase the exchange of technical assistance between States by providing additional money for travel by Regional and National staff, and finally, \$250,000 would go to provide awards to State staff members who are most responsible and successful in reducing their State's error rate.

Ms. VUCANOVICH. Like many of my colleagues on the Subcommittee, I have heard from organizations in my district who will have great difficulty providing nutritional services if the TEFAP budget is reduced. If the funding is reduced, what will your agency do to assist these helpful organizations who have come to rely on this funding?

RESPONSE. We are, in fact, not reducing administration funds that go to the States and organizations that distribute the Emergency Food Assistance Program (TEFAP) commodities and so many commodities provided by the private sector. As far as Federal food dollars go, although funds would not be appropriated under the budget to purchase food for TEFAP in Fiscal Year 1995, States will continue to receive "bonus" commodities, primarily of exclusively butter. According to the recently released Second Harvest Study, Federal, State and local Governments account for only about 5.1 percent of the food that programs in that network distribute. The vast majority comes from the private sector, which is well-equipped to support the food needs of what is essentially a stop-gap assistance system as opposed to the Department's characteristic food assistance programs, which provide a clearly targeted and defined benefit on a regular, dependable basis.

Although TEFAP contributes only a small fraction of the food distributed by Second Harvest affiliates, the Second Harvest Study indicates that organizations in its nationwide network rely on Federal, State and local Governments for more than 55 percent of the cash income they need to cover administrative costs. The President's request for \$40 million in TEFAP administrative funds, the same level appropriated for Fiscal Year 1994, demonstrates this Administration's commitment to the continuation of TEFAP distribution system. These funds can be used not only for the administrative costs associated with TEFAP commodities, but also for the administration of the Soup Kitchen/Food Bank Program, and the handling of non-USDA commodities distributed through the TEFAP network.

Mr. WELSH. I am very concerned about your agency's decision to, for all practical purposes, eliminate the TEFAP program. TEFAP commodity purchases help provide nutritional benefits to many low-income families who are unable to meet their nutritional needs through other domestic feeding programs. The \$40 million left in the program for administrative expenses will help distribute bonus commodities only if the Secretary determines that there are excess commodities. While I recognize that the (Agriculture) Department is facing severe budget constraints, why is the administration eliminating this proven program?

If this program is eliminated is there substantial overlap in other feeding programs that will ensure that families that have received TEFAP commodities in the past will continue to receive these benefits? Is there any administrative duplication in government feeding programs? Do you foresee any job losses in food banks as a result of your agency's decision?

What good does it do to provide increases in nutrition education training programs if low-income families are going hungry and not meeting their nutritional requirements in the first place. Shouldn't our government place a higher priority on ensuring that our constituents are fed?—Because without providing adequate funding for our feeding programs we can not provide the hungry with the correct nutritional requirements that they need.

RESPONSE. Although funds would not be appropriated under the budget to purchase food for TEFAP in Fiscal Year 1995, the Department will continue to support

the TEFAP network through the provisions of "bonus" commodities, primarily or exclusively butter, as well as \$40 million in administrative funding. In its traditional role as a surplus removal program, TEFAP has primarily disposed of surplus commodities, rather than meeting the specific nutritional needs of a clearly defined population. The assortment of commodities made available to TEFAP recipients provides an occasional dietary supplement, rather than a steady source of nutritional support upon which participants can depend. While more money would certainly purchase more food, we believe that limited resources should be directed where specific nutritional objectives are served and the results can be measured. The Food Stamp Program meets these criteria and continues to be the primary and most effective means of combatting hunger.

Households potentially impacted by the reduction in TEFAP foods can continue to meet their nutritional needs through the Food Stamp Program. In addition, these households may participate simultaneously in several of the programs targeted to specific subsets of the population, including the Special Supplemental Program for Women, Infants, and Children (WIC) or the Commodity Supplemental Food Program, the Child and Adult Care Food Program, the Nutrition Program for the Elderly, the Soup Kitchen/Food Bank Program, and the National School Lunch Program.

The diversity of Federal food assistance programs is not indicative of administrative duplication, but rather of our concerted efforts to reach all needy Americans. Taken together, the 15 programs form a network of basic assistance to meet the needs of most, through the Food Stamp Program, and supplemental assistance to meet the special nutritional needs of specific subsets of the population. Federal food programs deliver benefits in a variety of forms, through variety of institutions, and to a variety of target groups.

Given our continued support of TEFAP through the provision of administrative funds and bonus commodities, we do not foresee any job losses in food banks as a result of the discontinuation of purchased TEFAP commodities.

Inadequate nutrition for a given family may not be the result of inadequate Federal food assistance resources. Some low-income households may not be aware of the nutrition assistance that is available to them. The Department is addressing this issue through various outreach initiatives. There is also a complex relationship between a household's food supply, food knowledge, and management skills. For example, deficiencies in knowledge and skills may result in inefficient utilization of food stamps that results in a nutritionally inadequate food supply. As knowledge about selecting, purchasing, and preparing food improves, households become more efficient in utilizing the resources available to them for meeting their nutritional needs. The Department's ambitious proposal for expanded nutrition education efforts in conjunction with food assistance programs can provide the necessary knowledge and skills. Nutrition education can play a vital role not only in helping households meet their short-term nutritional needs, but can also contribute to life-long positive dietary habits that promote good health. Therefore, nutrition education has great potential as a means of reducing public health care costs. This potential is especially promising with regard to school children who learn about the relationship between diet and health in an educational setting.

The Department believes that nutrition education is thoroughly integral to food assistance, not a competing priority. It should also be noted that the Department is fully committed to more precisely determining the extent to which hunger currently exists in this country. To this end, the Food and Nutrition Service has executed an interagency agreement with the Bureau of the Census to conduct a Food Security Survey in April 1995 in conjunction with the current population survey. This effort will measure the key element of direct personal experience with food insecurity.

Mr. WALSH. The Electronic Benefit Transfer (EBT) Debit Card is a innovating new program that will help reduce fraud and abuse in the Food Stamp Program. New York State is planning on implementing this program starting in 1996 and I would love to speed up this timetable as I believe EBT is a cost effective program. However, New York State and other states have expressed concern over the potential impact of proposed regulations issued by the Federal Reserve Board. These regulations, known as regulation "E", addresses the issue of liability for credit cards that are reported stolen. If a consumer loses or has his credit card stolen, regulation "E" would state that the consumer is liable only for the first \$50 charged to his card. However, the Federal Reserve Board is trying to extend these regulations to public assistance and food stamp programs. Therefore, if someone else accessed your benefits, the consumer would lose the first \$50 in benefits. The question then remains as to who would be liable for benefits that are accessed above the \$50 level. Would the federal government have to pay for these duplicative benefits or would the state be liable for these benefits and forced to incur these losses. This is an important

question because if the states are liable then they would be faced with the prospects of huge financial penalties if unscrupulous individuals are able to access an individual's food stamp benefits. What does your agency plan to do to combat this potential problem and what is your agency's position on regulation "E"?

RESPONSE. We take the responsibility for ensuring consumer protection very seriously. However, we were opposed to the application of Reg E to EBT because of the costs we fear it will impose on EBT systems—in the form of liability claims and administrative burden—and the consequent chilling effect it might have on the future of EBT. We on the Federal Interagency EBT Task Force urged the Federal Reserve Board to provide a three year moratorium on the application of Regulation E to EBT and are pleased that the Federal Reserve recognized the complexity and potential costs of Reg E implementation by agreeing to that three-year period. During this three-year period, we will collect and evaluate data on actual Reg E costs in the EBT environment. We have already taken initial steps to design this evaluation. As part of this evaluation, we will develop policy guidelines, management controls to help prevent abuse, and operating rules that will allow us to project the effects of Reg E once fully implemented. Based on developments, we will recommend appropriate action, such as legislation and/or authority to fund the costs of full Reg E implementation.

Mr. DURBIN. Thank you for joining us today; we appreciate it very much.

Biography

ELLEN HAAS

Assistant Secretary of Agriculture
for Food and Consumer Services

Ellen Haas was nominated by President Bill Clinton to be assistant secretary of agriculture for food and consumer services on April 2, 1993, was confirmed for that position by the U.S. Senate on May 26 and was sworn in on May 28.

As assistant secretary of agriculture for food and consumer services, Haas manages USDA's Food and Nutrition Service, the Human Nutrition Information Service, and the Office of the Consumer Advisor, and is therefore responsible for the Department's primary food assistance programs and nutrition education.

Before joining USDA, Haas served for over ten years as executive director of Public Voice for Food and Health Policy, a Washington, D.C.-based consumer research, education, and advocacy organization whose mission is to promote a safer, healthier, and more affordable food supply. She founded the group in 1982.

From 1976-82 Haas was director of the Consumer Division of the Community Nutrition Institute, based in Washington, D.C. From 1975-76 she was acting executive director of the National Consumers League. She worked as the director of consumer education for Montgomery County, Md., from 1973-74. She taught high school American history and government in Oklahoma City, Okla., from 1961-63.

Haas was elected for five terms as president of the Consumer Federation of America, and for ten terms as vice president. She was a board member of the organization 1974-93. She founded the Maryland Citizens Council in 1973 and served as its president 1973-75. From 1987 to 1991, she served as a member of the board of directors of Second Harvest, the national organization of food banks, and from 1986 to 1990 was a member of the board of directors of the Coalition for Consumer Education. In addition, for the past 20 years she has been selected to represent consumers on a number of federal advisory boards.

A native of New York City, Haas holds a B.A. degree in history from the University of Michigan in Ann Arbor.

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May 1993

**William E. Ludwig
Administrator, Food and Nutrition Service
U.S. Department of Agriculture**

In December 1993, William E. Ludwig was appointed Administrator of the Food and Nutrition Service. Prior to joining the Agency, Mr. Ludwig served as Deputy Secretary for the Louisiana Department of Social Services under both the previous and current Governors.

Mr. Ludwig began his career in State government as Vice Chairman of the Louisiana Welfare Reform Task Force which was responsible for redesigning the State's welfare system in accordance with Federal regulations. He served as Chairman of the Louisiana Child Care and Development Task Force which was responsible for designing the Child Care Assistance and Child Care At Risk Programs as well as Chairman of the Child Care Council which is responsible for upgrading all child care facilities in the State. Mr. Ludwig was also responsible for the design and development of Louisiana's Electronic Benefit Transfer system.

Mr. Ludwig is a graduate of Louisiana State University, where he received his Bachelor of Science Degree in pre-law/business. He also received a Masters in Business Administration from Louisiana Tech University.

For Release only by the
House Committee on Appropriations

UNITED STATES DEPARTMENT OF AGRICULTURE
Food and Nutrition Service

Statement by Ellen Haas, Assistant Secretary
for Food and Consumer Services
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration and Related Agencies

Thank you, Mr. Chairman. I am pleased to be here today to offer the Administration's vision for our programs in the Food and Nutrition Service for the coming fiscal year. We appreciate the opportunity to discuss President Clinton's and Secretary Espy's convictions that all Americans, especially our children, should have access to food that is nutritious and healthful. I would like to introduce Mr. William Ludwig, Administrator for the Food and Nutrition Service (FNS), who is with me here today, and enter his biographical statement into the record.

Our budget request mirrors President Clinton's efforts to put children, nutrition, and health at the top of the Nation's agenda. FNS appropriations, for the current Fiscal Year, total \$39.5 billion, including a \$2.5 billion reserve for the Food Stamp Program. The Programs have had, and continue to have, strong bipartisan support for their traditional roles of providing access to food for needy Americans. But, in order for this support to continue, our programs must be fiscally sound,

reduce the potential for program abuse, utilize new technologies, respond to our clients needs, and reflect the new nutrition priorities of the 1990s.

At the new USDA, feeding hungry people is a top priority. Secretary Espy and I are committed to fighting hunger.

We are staunch supporters of the programs we administer. In 1995, 65 percent of USDA's budget will be dedicated to the 15 food and nutrition programs I oversee.

We have a firm resolve that no one in our nation should fear hunger. And this budget honors that commitment. The Fiscal Year 1995 Budget requests \$40.3 billion for the administration of USDA's food assistance programs; an increase of nearly \$1 billion above the Fiscal Year 1994 level.

Another way USDA is fulfilling its commitment is through the Mickey Leland Childhood Hunger Relief Act, which became law last year. The President's budget requests \$0.3 billion to continue implementing the Leland Act in the Food Stamp Program. I have set up a Task Force to expedite the speedy implementation of the Leland legislation.

As this committee knows, one of the major innovations of the Clinton Administration will be to change the way we deliver Food Stamp benefits through modern technology with the use of Electronic Benefits Transfer (EBT). This will replace the inefficient coupon system currently in effect. EBT has been shown to be cost-effective and has major implications for program integrity and improvement. EBT provides dignity for recipients, more convenience for retailers, and more accountability for program administrators. The goal is to make EBT nationwide in the fullest sense -- One-card, user-friendly, unified delivery of Government funded benefits.

This budget requests \$10.6 million to continue to move aggressively toward implementation of EBT in our Food Stamp Program.

The budget also provides funding for improvements in program integrity which we believe is very important in the delivery of Food Stamp Program benefits.

The President's budget is also a budget that invests in children.

President Clinton's commitment to achieve full funding for WIC ensures that by the end of Fiscal Year 1996 every eligible woman, infant and child who seeks the benefits of WIC's nutrition assistance, health screening and counseling, will be able to

receive it. I want to thank you, Mr. Chairman, for your diligent and tireless leadership toward the goals of full funding for the WIC Program.

The Fiscal Year 1995 budget calls for \$3.6 billion, an increase of \$354 million, or 11 percent, above the Fiscal Year 1994 budget. This increase will help to fund an additional 700,000 participants per month, bringing average WIC participation to approximately 7.2 million participants each month.

WIC has been successful, in part, because nutrition education has been built into the program. We need to build on that initial investment in our children's health.

Eating habits are firmly established by the age of 12, so programs that deliver meals to children become a critical tool for developing life-long dietary patterns.

The Department of Agriculture has a national health responsibility in this area, so we have been leading a national effort to improve the nutritional standards of the meals we serve school children.

Our National School Lunch Program serves 25 million children each day in more than 92,000 schools. Half of those meals go to low-income children, and may be their only nutritious meal of the day.

Children -- especially poor children -- need to get a certain number of calories, vitamins and minerals for physical and cognitive growth. These are the minimum essentials.

In addition, childhood obesity and other diet-related problems are particularly severe for low-income, minority children, and have long-term health consequences. So Secretary Espy and I both understand that we have a special responsibility to provide meals to children that make a positive contribution to their health.

We heard these points -- and other facts about the critical link between diet and health -- during our four national hearings on "Nutrition Objectives for School Meals," over which I presided last fall. More than 350 witnesses testified, and we received more than 2,300 written comments.

The hearings have provided a record with a compelling call for change.

USDA is planning a comprehensive, integrated approach to meet the challenge of providing nutritious, appealing school meals as economically as possible.

As we develop this approach, we are guided by five principals.

First, healthy children: We must provide our nation's children with access to a school lunch program that promotes health, and meets the Dietary Guidelines for Americans. As you know, Mr. Chairman, the Dietary Guidelines are the nation's policy for what constitutes a healthful diet. They are jointly issued, and revised every five years, by USDA and the Department of Health and Human Services.

Second, customer appeal: If food doesn't look good or taste good, children won't eat it. And we need to support the changes we propose with a national campaign of nutrition education, aimed at children using media they understand, in a language they speak.

Third, flexibility: Throughout our hearings, school food service professionals testified about the complexity of administering the school meal programs. We need to reduce the burden of paperwork, streamline reporting systems, recognize regional and economic differences, and offer schools flexibility in designing menus that meet dietary guidelines.

Fourth, investing in people: We've heard a consistent call from schools for training and technical assistance. To accomplish this the Fiscal Year 1995 budget requests approximately \$30.8 million for school nutrition education and training programs, to help schools comply with the recommendations of the Dietary Guidelines.

Finally, we must look for innovative ways to maximize resources, increasing cost effectiveness, optimizing purchasing power, and building partnerships with program stakeholders.

Mr. Chairman, the domestic food assistance programs that I have the privilege of administering provide millions of needy children and adults with access to the nation's abundant food supply. These programs help nearly 40 million needy Americans and low-income people put food on their plate and achieve nutritious diets. We estimate that one out of every six Americans is served through the programs managed by the Food and Nutrition Service. We must continue to provide this access. With what we know now about the link between diet and health, we must extend the reach of these programs by providing the education and assistance necessary for all Americans to make nutritious food choices. The Fiscal Year 1995 budget request of \$40.3 billion for food assistance programs is essential if we are to reach this goal.

With your permission, Mr. Chairman, I would now like to ask Mr. Ludwig to make his presentation. Afterwards, we will be pleased to answer any questions the Committee may have.

Thank you.

For Release only by the
House Committee on Appropriations

UNITED STATES DEPARTMENT OF AGRICULTURE
Food and Nutrition Service

Statement of William Ludwig, Administrator
Food and Nutrition Service
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration and Related Agencies

Thank you, Mr. Chairman. It is a pleasure for me to appear before this subcommittee to discuss the 1995 budget proposed for the food assistance programs administered by the U.S. Department of Agriculture. I would like to introduce key members of the staff of the Food and Nutrition Service appearing with me: George Braley, Associate Administrator of the Food and Nutrition Service; Bonny O'Neil, the Acting Deputy Administrator for the Food Stamp Program; Janice Lilja, Associate Deputy Administrator for the Special Nutrition Programs; Michael Fishman, Acting Director of The Office of Analysis and Evaluation; and Kenneth Bresnahan, Acting Deputy Administrator for Financial Management. I am appearing before the committee for the first time. In keeping with committee policy, I would like to place my biographical statement into the record at this time.

MISSION OF THE FOOD AND NUTRITION SERVICE

The mission of the Food and Nutrition Service (FNS) is to alleviate hunger and safeguard the health and well-being of the Nation through the administration of domestic food assistance programs and nutrition education. The Food and Nutrition

Service is the Federal Government's front-line in providing food assistance to the most needy and vulnerable of our citizens. Established in 1969 to administer the domestic food assistance and nutrition education programs of the Department of Agriculture, FNS works in partnership with State and local governments to perform its mission.

SIZE, ORGANIZATION, AND LOCATION

Fiscal Year 1994 appropriations for the Food and Nutrition Service total \$39.5 billion, in eight accounts covering fifteen programs and Federal administrative expenses. FNS is allocated 1,921 staff years funded from the Food Program Administration, Food Stamp and Child Nutrition accounts.

The Food and Nutrition Service's appropriation represents over 60 percent of the budget authority of the U.S. Department of Agriculture. Over two-thirds of the FNS appropriation is used to fund the Food Stamp Program. Over 99 percent of the total appropriation is used for recipient benefit payments or grants to States for their administration of the programs. Less than one percent of the overall appropriation pays for direct Federal administrative expenses of the Agency. The Food and Nutrition Service employs less than two percent of the people who work for the USDA.

About one-third of FNS employees are stationed at the headquarters office in Alexandria, Virginia. These staff are engaged primarily in program policy and regulatory development, program research and evaluation, information resource management, financial management and certain other centralized administrative support functions. The other two-thirds of the staff are located in seven regional offices and 84 field offices nationwide. These personnel work closely with State and local cooperators to implement and monitor the programs, and work with retailers who seek authorization to redeem food stamps. FNS also has six food stamp compliance offices that investigate firms suspected of abusing the program.

I will provide for the record a copy of the current Agency organization chart and geographic staff allocation.

FISCAL YEAR 1994 BUDGET OVERVIEW AND CURRENT ACTIVITIES

As I mentioned earlier, for Fiscal Year 1994, the Food and Nutrition Service appropriation totaled \$39.5 billion, including Food Stamp Program reserves. This level of funding allows FNS to emphasize program integrity and concentrate on improving efficiency in the delivery of benefits to recipients and integrating nutrition into our food assistance programs. Major areas of emphasis include:

In the Food Stamp Program --

- o Implementation of the Mickey Leland Childhood Hunger Relief Act, P.L., 103-66, which made many necessary improvements in the Food Stamp Program.
- o Implementation by State agencies of Food Stamp Program Electronic Benefit Transfer (EBT) plans, and participating in interagency efforts to develop a multi-State EBT prototype.
- o Implementation of strategies to increase and enhance Food Stamp Program retailer integrity enforcement actions.
- o Implementation of strategies to reduce errors caused by recipients and State agencies; in Fiscal Year 1992, such errors resulted in erroneous over issuance of \$1.7 billion in food stamp benefits.

In the WIC Program --

- o Continuing efforts toward achieving full funding for the WIC Program to ensure all eligible persons can be served by the end of Fiscal Year 1996. It is estimated that about 7.5 million persons would apply for WIC Program benefits when fully funded.
- o Promoting breastfeeding, immunization, smoking cessation and developing an exit counseling brochure for those recipients no longer eligible for the Special Supplemental Food Program for Women, Infants and Children (WIC).
- o Continuing implementation of the Farmers' Market Nutrition Program and Public Law 102-512, the WIC Infant Formula Procurement Act of 1992.

In the Child Nutrition Programs --

- o Undertaking a comprehensive initiative to promote the health of children by improving the nutrition quality of school meals so that they meet the U.S. Dietary Guidelines. This will include nutrition education and training, technical assistance, streamlining administration as well as program policy changes.

- o Continuing operations and expanding the homeless demonstration project to evaluate the feasibility of providing Federal child nutrition funding for meals served to children in homeless shelters.

STREAMLINING THE AGENCY

Consistent with the President's directive dated September 11, 1993, recommendations of the Vice President's National Performance Review, and the Secretary's reorganization plan, FNS is developing plans to streamline its operations, increase efficiency, and minimize bureaucracy. Specifically:

- o The Office of Consumer Advisor is being merged into FNS as a staff office reporting to the Administrator.
- o All functions managed by the Assistant Secretary for Administration and the Chief Financial Officer at the Department level will be mirrored in the functional assignments of the Deputy Administrator for Management and the Comptroller at the Agency level.

- o Total staffing levels have already been reduced in Fiscal Year 1994 from 1,979 to 1,921. These reductions and further reviews of Headquarters staffing levels will be followed by reviews at field and regional offices. Assistant Secretary Ellen Haas and I will be making specific recommendations with regard to field office changes in addition to current plans to close several offices.
- o Personnel requirements will be reduced through reorganization and improvements and efficiency. Staffing levels will be reduced from 1,921 to 1,915 in Fiscal Year 1995 and to 1,850 by the end of 1998.

FISCAL YEAR 1995 BUDGET PRIORITIES

Mr. Chairman, we appreciate the opportunity to discuss the Fiscal Year 1995 budget proposed for the Food and Nutrition Service. This budget reflects the highest overall funding ever requested for the domestic food assistance programs. The amount requested will enable us to serve record numbers of participants in our programs. The President and Secretary of Agriculture have clearly made nutrition a top priority as part of the goal to improve the health of all Americans. Food assistance to the needy is inseparable from nutrition and health, and we have increased our commitment to providing program support to fight

hunger and improve the health of America's neediest citizens. The budget I present to you today recognizes the critical importance of continued support for food assistance programs, and reflects the President's and the Secretary's goals for the Food and Nutrition Service.

Mr. Chairman, we have worked particularly hard over the past few months to balance our goals with some challenging budget realities. My responsibility, as Administrator, is to see that these record budgetary resources are spent responsibly and wisely. The balance that we have achieved is reflected in the budget that we are presenting here today. Some of the key proposals for Fiscal Year 1995 that I will describe include:

- o Continued support for aggressive implementation of Electronic Benefit Transfer (EBT) in the Food Stamp Program, that will move us closer to initiating EBT in all States by the end of 1996. This support underscores Secretary Espy's and Assistant Secretary Haas' commitment to improve efficiency and integrity in all the food assistance programs. EBT is the kind of measure President Clinton's economic plans and new government encourage;

- o Supporting the Administration's goal to improve the health of all Americans by moving toward full funding of WIC through the largest level of funding ever requested for WIC by any President. Food assistance and nutrition assistance are inseparable issues and are inextricably linked to the Administration's health care priorities. This makes WIC all the more important as it improves participants' nutritional status while also serving as a vital "gateway" to other important health services;
- o A significant increase for implementation of the Dietary Guidelines for Americans to improve school meals through an investment in nutrition education and technical assistance. USDA is leading a national effort to improve the nutritional standards of the menus we serve school children. Our goal is healthy children. We must offset the nutritional neglect of the recent past with a new era of nutritional responsibility;
- o Making nutrition a priority as a part of the goal of improving all American's health. That makes it important to provide nutrition education and information to our customers. The food assistance programs offer an excellent platform for encouraging

those who need to do so to learn about nutrition and, in particular, to follow the Dietary Guidelines; and

- o Increased emphasis on integrity, accountability and efficiency in the food assistance programs. The programs are being reviewed to better emphasize the traditional values of work, family, opportunity, and responsibility.

In addition, this budget provides sufficient funding under current law to meet the expected increases for inflation and program participation for our mandatory programs. I cannot emphasize enough the importance of these programs to needy Americans.

Legislative changes in the form of the Mickey Leland Childhood Hunger Relief Act, passed by Congress in 1993, increased food stamp benefits to especially vulnerable Food Stamp recipients, such as households with children or with very large shelter costs. And, every day millions of children and elderly Americans receive meals through USDA's Child Nutrition Programs. These programs provide meals, including reduced-price or free meals for those most in need.

FISCAL YEAR 1995 BUDGET OVERVIEW

The Food and Nutrition Service requests \$40.3 billion in new budget authority for Fiscal Year 1995, including Food Stamp Program reserves. This is an increase of almost \$1 billion above the Fiscal Year 1994 appropriated level, and while some of this increase is driven by inflation, it is a declaration of the importance USDA places on the health of our citizens. The most significant increases have occurred in the WIC program and the mandatory Food Stamp Program account.

FOOD STAMP PROGRAM

The Food Stamp Program is the cornerstone of USDA's food assistance programs, helping to put food on the table for more than 27 million Americans each month. For the Food Stamp Program, we are requesting an appropriation of \$27.7 billion, including reserve funding to ensure that funds are available to meet any unanticipated increases in program needs. The amount of this request is based on our best projections under current law and government-wide economic assumptions. Our projections suggest that:

- o The rate of unemployment will average 6.6 percent in 1994, declining slightly to 6.2 percent in 1995;

- o Program participation will decrease slightly to 27.3 million average monthly participants in 1995 from 27.4 million in 1994;
- o The Thrifty Food Plan and the related maximum benefit will increase significantly. This, in combination with benefit increases in the Mickey Leland Childhood Hunger Relief Act, results in a more than \$3 increase in average monthly per person benefits to \$71.60.

We are asking the Committee's consideration for an appropriation that would include a \$2.5 billion reserve in the event that program growth overwhelms our current performance estimates. I know that you and I agree, Mr. Chairman, on the critical importance of the Food Stamp Program as a life-line for needy people. In addition, we are seeking both a first quarter advance appropriation for Fiscal Year 1996 and an indefinite authority for the Food Stamp Program. Each of these mechanisms will help ensure the efficient and uninterrupted delivery of food stamp benefits. We should do everything we can to make sure sufficient funding for this program is secure.

ELECTRONIC BENEFIT TRANSFER

The 1995 budget proposal will allow FNS to continue to move aggressively toward implementation of Electronic Benefit Transfer

where cost effective. EBT is an electronic system for transferring food stamp benefits from a recipient's account to a retailer's account.

Continued support of EBT underscores Secretary Espy's and Assistant Secretary Haas's commitment to improve efficiency and integrity in the food assistance programs. EBT is just the kind of efficiency measure President Clinton's economic plans and Administration encourage. It was highlighted in the report of Vice President Gore's National Performance Review, and recent studies have shown that EBT can lower operating costs. As an example, one recent study shows that Government issuance costs dropped, costs to retailers dropped, and recipient costs, such as those associated with lost benefits, were lower with EBT than under the coupon system.

Of equal importance to the cost effect of EBT is the effect EBT has on food stamp recipients. In each of our evaluations, recipients have enthusiastically embraced this new benefit delivery system as one that removes the stigma of using paper food stamps and one that affords them much more security over their benefits than they had with paper food stamps.

Today, there are approximately 224,000 households using over \$40 million in food stamp benefits each month via EBT at 3,750 retail food stores. Throughout Fiscal Year 1994, we expect to see EBT

increases as projects expand to serve about 270,000 households by delivering \$49 million in benefits each month. The figures for Fiscal Year 1995 will increase substantially as States that are now in the bid process or that have just signed contracts begin to bring up their EBT systems. Maryland has been operating EBT Statewide since April 1993, and there are EBT systems currently operating in Reading, Pennsylvania; Bernalillo County, New Mexico; Ramsey County, Minnesota; Linn County, Iowa; Camden County, New Jersey; and Dayton, Ohio. Another 25 States have expressed interest in EBT and are in the process of planning or developing their systems. Federal staff continue to work with States by providing technical assistance and reviewing documentation. We are also pursuing a standard system for settlement and reconciliation of EBT payments with the Department of Treasury and the Federal Reserve. A standard settlement system, an analog to the one currently operated by the Federal Reserve for the Food Coupon redemption system, is one of the items necessary for large-scale EBT operations.

By eliminating paper coupons and creating an electronic record of every food stamp transaction, EBT will be a useful tool in improving program delivery and in reducing certain types of food stamp fraud and trafficking. Selling or trading benefits through a third party will be more difficult with EBT because of the need for a system access terminal, the recipient's EBT card and personal identification number to determine the amount of

benefits to sell. EBT also enhances control of trafficking by providing an audit trail that supports both detection and prosecution of benefit diversions. However, EBT provides new opportunities for fraud, therefore we will continue working with our OIG and others involved in EBT to make every effort to ensure the integrity of the EBT system.

FOOD STAMP PROGRAM ERROR REDUCTION

In Fiscal Year 1992, 8.19 percent of food stamp benefits were overissued and 2.5 percent were underissued for a total error rate of 10.69 percent. This represents a net loss to the program of \$1.2 billion. We must continue to pursue improved payment accuracy rates as a high priority activity. In Fiscal Years 1993 and 1994, participation has increased even as many States reduced budgets and staffing levels. In an attempt to assist State efforts to improve payment accuracy, FNS is requesting an increase of \$1 million for error reduction activities which will provide an increased Federal presence (of 5 staff years) in working with the States to substantially improve their management oversight and administration of the Food Stamp Program.

FOOD STAMP INTEGRITY

The Mickey Leland Childhood Hunger Relief Act expanded benefits to those most in need, but also toughened penalties for people

who try to cheat the system. Several initiatives are proposed in this budget to increase integrity in the Food Stamp Program. This budget increases our emphasis on integrity, accountability and efficiency by expanding the Federal Tax Refund Offset Program and improving the accuracy of payments to recipients through increased technical assistance to States. This year, approximately \$100 million in claims are expected to be referred to the Internal Revenue Service for collection, yielding a projected savings to the government of well above \$20 million.

FOOD STAMP TAX OFFSET EXPANSION

We are working hard to strengthen the agency's debt collection methods. One method being tested collects overissued food stamp benefits from Federal income tax refunds of individuals who received such excess benefits because of fraud or providing erroneous information. These individuals are no longer participating in the program. In 1992, the first year of the test, we collected more than \$3 million in offsets from the two States involved. Voluntary payments provided an additional \$400,000. In 1993 we added seven States, and collections, both offsets and voluntary payments, totaled \$8.5 million. We have added another 12 States in 1994, which brings us to a total of 21 States. We estimate that program-wide use of tax offset would result in \$25 - \$40 million collected each year. There is currently more than \$600 million in debt for overissued food

stamp benefits due to fraud and erroneous information, and a significant portion of this could be collected through Federal income tax offsets.

NUTRITION EDUCATION

This budget also makes nutrition a priority in the Food Stamp Program. Through this budget request, FNS will continue to provide matching funds for State nutrition education and will also test, within our research account, new programs to integrate nutrition education into the Food Stamp Program. FNS is conducting nutrition education demonstration grants to support development, implementation and evaluation of creative community nutrition intervention programs directed toward food stamp participants.

NUTRITION ASSISTANCE FOR PUERTO RICO

The budget request for Nutrition Assistance for Puerto Rico is \$1.143 billion, an increase of \$52 million over the amount appropriated for Fiscal Year 1994. This is the maximum amount authorized.

INCREASED COMMITMENT FOR WIC

In keeping with the President's commitment to reach full funding

for the WIC program by the end of Fiscal Year 1996, the Fiscal Year 1995 budget proposes a substantial funding increase for WIC. We appreciate the consistent support that this Committee has shown for WIC over the past several years. For Fiscal Year 1995, the request totals \$3.56 billion compared to \$3.21 billion appropriated for this fiscal year. With this increase, WIC's average monthly participation would increase to about 7.2 million, an increase of about 0.7 million from the projected Fiscal Year 1994 average. This increase reflects a fundamental commitment to the welfare of children whose circumstances fail to provide the kind of nutrition needed for good health and normal growth.

NUTRITION EDUCATION INITIATIVE

Food assistance and nutrition assistance are inseparable issues, and are closely linked to the Administration's health care priorities. Recent studies have demonstrated that low-income persons -- those most likely to participate in the food assistance programs -- are at greatest risk for diet-related diseases. That makes WIC that much more essential as it provides nutrition education and counseling to those customers, improving their nutritional status at a fraction of the cost of other programs.

Through the WIC Programs FNS will continue to emphasize nutrition

education and training targeted at the WIC population. Funds for nutrition education and training are an integral part of state WIC grants, and total over \$150 million.

The Food and Nutrition Service is the primary USDA funding source for nutrition education for targeted high-risk groups.

Historically, most of this funding has been used to provide nutrition education through the WIC Program, and the 1995 budget request will allow WIC nutrition education to keep pace with the overall growth of the program.

WIC INFANT FORMULA REBATES

Infant formula rebates negotiated by States and manufacturers are a critical component of the cost effectiveness of the WIC Program. Through expanded multi-State bidding WIC has achieved greater savings than ever. WIC infant formula rebate revenues for Fiscal Year 1994 are projected to be over \$900 million and will support nearly 1.5 million participants, about one-fifth of projected WIC participation. In October 1992, Public Law 102-512 was signed for the Infant Procurement Act. This legislation required the Department to conduct bid solicitations for infant formula rebates on behalf of a group of States, if requested to do so. FNS is now preparing bid solicitations that will be released this spring.

BREASTFEEDING PROMOTION

USDA has traditionally played a significant role in promoting and supporting breastfeeding among WIC participants. In recent years, USDA has actively undertaken a number of initiatives in further support of this important health practice, including sponsorship of a Breastfeeding Promotion Consortium (BPC) of health professional, government and advocacy organizations mutually interested in breastfeeding. USDA is developing an initiative to promote breastfeeding among the general public and others who influence a woman's infant feeding decision. As GAO recently pointed out in its report "WIC's Efforts to Promote Breastfeeding Have Increased," FNS' efforts are beginning to pay off. Since 1990, the rate of in-hospital breastfeeding for WIC, breastfeeding at 1 month and 3 months, have all increased by approximately 12 percent. This reverses a 10 year trend downward. Our ultimate goal is to increase the level to at least 75 percent of the proportion of mothers who breastfeed their babies in the early postpartum period.

IMMUNIZATION PROMOTION

For the last 3 years, USDA has worked very closely with the Centers for Disease Control and Prevention (CDC) to increase immunization rates among preschool-age WIC participants. Numerous activities are occurring at all levels of program

operation to promote timely immunization. These various strategies seem to be having a positive effect.

WIC NON-SMOKING INITIATIVE

In the past 2 years, FNS has developed over \$1 million worth of materials (videos, professional guides, posters, and participant brochures) to meet a 1988 legislative mandate that WIC provide information on the effects of alcohol, tobacco and other drug use during pregnancy. A 1994 mandate specifically requires WIC to give women, as they leave the program, information on several nutrition and health issues, including the dangers of tobacco use and exposure to secondhand smoke. Efforts to meet the 1994 mandate include: 1) updating a brochure entitled "How WIC Helps" directed to pregnant women; 2) developing a brochure, tentatively entitled "After You Deliver: Health Tips for Moms"; and 3) purchasing from the March of Dimes, for distribution in WIC, a brochure that focuses on the dangers of smoking during pregnancy and the harmful effects of secondhand smoke on children. The latter will be used to supplement the smoking cessation messages in "After You Deliver."

CHILD NUTRITION PROGRAMS

For the Child Nutrition Programs, we are requesting a total of \$7.5 billion for Fiscal Year 1995. These funds are required to

meet the payments authorized under current law for subsidies providing free, reduced price and paid lunches, breakfasts and snacks to eligible participants in schools, summer programs, and child and adult care centers. As I'm sure the Committee is aware, several provisions of the School Lunch and Child Nutrition Acts expire at the end of Fiscal Year 1994. Our budget assumes and requests the reauthorization of WIC, the Summer Food Service Program, and authority to continue providing State Administrative Expense funds.

Projected funding for Fiscal Year 1995 provides an overall decrease in budget authority of \$46 million below the current year. This decrease is offset with significant carryover funds and will support increased meal service in each component of the account.

Millions of children receive meals everyday through the Child Nutrition Programs. The programs provide meals for children and some elderly adults when they are in school or day care, including reduced-price or free meals for those who qualify.

NUTRITION EDUCATION AND TECHNICAL ASSISTANCE

This budget proposes to increase spending in the Child Nutrition Programs for education, training and technical assistance for providers and children to prepare and eat school meals which meet

the recommendations of The Dietary Guidelines for Americans.

In recent years, there has developed a scientific consensus that we must be concerned with more than Recommended Dietary Allowances. The Dietary Guidelines for Americans are the federal policy on what makes a healthful diet, established in 1980 by USDA and the Department of Health and Human Services.

In 1990, the Dietary Guidelines were revised to include recommendations that not more than 30 percent of calories come from fat and not more than 10 percent of calories come from saturated fat. Reinforcement of the recommendations to apply these limits to the diets of children was issued by the American Academy of Pediatrics in September 1992 and by the American Dietetics Association in March 1993.

A recent USDA study of school meals showed we are doing an excellent job of providing one third or more of the RDA for essential vitamins and minerals and the recommended number of calories. Unfortunately, the study also showed that school lunches exceed the Dietary Guidelines for fat by 25 percent, saturated fat by 50 percent, and sodium by nearly 100 percent.

Approximately \$30.8 million in the proposed budget will go to school nutrition education and training programs, and to help school food authorities comply with the Dietary Guidelines for

Americans.

The budget proposal includes an increase of \$18.4 million in the Child Nutrition Programs to provide nutrition education tools for States, increase FNS' capacity to provide technical assistance to States, and to help school food authorities comply with the Dietary Guidelines. At our four public hearings, we heard a consistent call for training and technical assistance. If food doesn't look good and taste good, children won't eat it. So we want to invest in the people who participate in and administer the programs.

Funds will support all child nutrition programs and provide training on menu analysis and assessment, menu planning, technical aids, recipe development, and other forms of technical assistance for school districts to meet the Dietary Guidelines. The funds will also allow the Secretary to develop national nutrition education projects to school-age children.

The Nutrition Education and Training Program (NET) develops nutrition education programs and instructs food service workers and teachers in nutrition and health. FNS proposes a total of \$10.3 million for NET, the same level funded in Fiscal Year 1994. This NET funding is an important component of a comprehensive multi-year initiative to implement the Dietary Guidelines in the Child Nutrition Programs by the year 2000, and is needed to teach

children how to make healthful food choices and assist food service staff in producing improved meals in school.

CHILD NUTRITION MEALS

The Fiscal Year 1995 budget will provide meals to approximately 25 million children daily in the National School Lunch Program, over half of whom receive their meals free or at a reduced price. The 1995 estimate for the school lunch program is \$4.4 billion, up from \$4.3 billion in 1994. The School Breakfast Program will provide meals to approximately 5.9 million children, of whom more than 5 million receive their meals free or at a reduced price. Estimated spending will total over \$1 billion for the breakfast program in 1995, up from \$950 million in 1994.

The Child and Adult Care Food Program serves approximately 2 million children and adults on a daily basis. Anticipated spending for the Program will total \$1.6 billion in 1995, up from \$1.5 billion in 1994. About one-half of child care meals will be served in day care centers including Head Start Centers and one-half of the meals will be served in family day care homes.

The Summer Food Service Program last summer served meals to just over 2 million children a day. Anticipated spending for the Summer Program will total \$256.6 million for 1995, up from \$232.9 million in 1994.

SPECIAL MILK PROGRAM

We are requesting a total of \$18.1 million under current law for the support of the Special Milk Program. This is a decrease in the appropriation of \$2.2 million from Fiscal Year 1994. However, \$1.6 million of carry over funds will be used to operate this Program at a \$19.7 million level in Fiscal Year 1995.

Current estimates for inflation and participation rates indicate that the requested level will support our expected increase in reimbursement rates and anticipated slow participation growth.

COMMODITY SUPPLEMENTAL FOOD PROGRAM

For Fiscal Year 1995, the President's Budget requests \$94.5 million for the Commodity Supplemental Food Program, the same as was requested in Fiscal Year 1994 and somewhat less than the Fiscal Year 1994 appropriation. Fiscal Year 1994 funds support a caseload of 257,000 women, infants and children, and almost 174,000 elderly participants. The 1995 budget will maintain services to its primary target population: women, infants and children.

FOOD DONATIONS PROGRAMS FOR SELECTED GROUPS

The Food Donations Programs for Selected Groups support the Food

Distribution Program on Indian Reservations (FDPIR), Nutrition Programs for the Elderly (NPE), Commodities for Soup Kitchens, the remaining support for the Trust Territories in the Pacific, and disaster assistance. The budget request is \$230 million. The budget increases direct spending for Soup Kitchens and Food Banks to help offset a decrease in other commodities available for donations. It funds a food assistance program for American Samoa for the elderly, blind and disabled which will help persons not helped by the Child Nutrition Program block grant already functioning there. The budget requires a slight decrease in per meal reimbursements in NPE, but maintains participation at the Fiscal Year 1994 level. The budget also supports the Fiscal Year 1994 level of participation in FDPIR in Fiscal Year 1995 through carryover of funds and inventory drawdown.

THE EMERGENCY FOOD ASSISTANCE PROGRAM

The budget requests \$40 million in administrative funds to continue the TEFAP distribution network. The TEFAP network will allow the distribution of bonus commodities and facilitate efforts to help provide for the basic food needs of low-income Americans. Funds will allow the continued distribution of prepared meals supported by USDA commodity donations to Soup Kitchens and Food Banks and household distributions of commodities provided by a variety of private sources. Funds are not requested to purchase commodities for The Emergency Food

Assistance Program (TEFAP) in part for budgetary reasons, but also in recognition that food stamp benefit levels have been increased. However, States will continue to receive bonus commodities for distribution as well as the administrative funds to support their infrastructure. FNS will work with industry and community groups to promote and encourage increased food donations as well as referrals to the Food Stamp Program, which is our mainstay in the fight against hunger.

In addition, the Omnibus Budget Reconciliation Act of 1993 provides \$230,000 for a continuation of TEFAP demonstration projects in Kentucky and Vermont. The demonstration will test commodities that are low in sodium, fat and sugar, and commodities with high nutrient value.

FOOD PROGRAM ADMINISTRATION

Critical to the achievement of all of these objectives are the administrative funds of the Agency. For Fiscal Year 1995, we are requesting \$107 million, a decrease of \$784,000 from Fiscal Year 1994.

This level of funding is critical to allowing the Agency to meet its mission and maintain program operations at an efficient and effective level. This budget includes a reduction of three percent in staffing from Fiscal Year 1993 levels by the end of

Fiscal Year 1995 in support of the President's Executive Order mandating a reduction of 252,000 Federal positions by the end of Fiscal Year 1998.

Mr. Chairman, we have made extraordinary efforts in the Food and Nutrition Service to meet the challenges of growing food assistance programs, at the same time working harder with less. The level requested in this budget will support our mission of safeguarding the health and well-being of our Nation through the administration of the domestic food assistance programs.

This summarizes the Fiscal Year 1995 budget request of the Food and Nutrition Service. I will be happy to answer the Committee's questions.

FOOD AND NUTRITION SERVICE

Purpose Statement

The Food and Nutrition Service (FNS) was established August 8, 1969, by Secretary's Memorandum No. 1659 and Supplement 1 pursuant to the authority contained in 5 U.S.C. 301 and the Reorganization Plan No. 2 of 1953.

The Food and Nutrition Service administers food assistance programs which provide access to a more nutritious diet for persons with low incomes and which encourage better eating patterns among the nation's children. The programs are:

Food Stamp Program. Food stamps are issued to eligible low-income households to enable them to obtain a better diet by increasing their food purchasing power. The program is a Federal-State partnership with the Federal Government paying the full cost of food stamps. The Federal Government also funds over half of the expenses incurred by the States to administer the program, including recipient household certification, food coupon issuance and employment and training activities for recipients. Funds for this program are provided by direct appropriation.

Nutrition Assistance for Puerto Rico. This program provides grant funds to the Commonwealth of Puerto Rico to operate a food assistance program specifically tailored to the needs of its low-income citizens provided that the program assures assistance for the most needy persons in the jurisdiction. Puerto Rico has established eligibility standards and administrative mechanisms approved by FNS to assist low-income households with cash grants, rather than food stamps or coupons. This assistance is intended to supplement recipients' income to help them purchase food for an adequate diet. A small portion of the grant is also used to stimulate local food production and distribution activities through a Tick Eradication Program. Another small portion is used to fund a Special Wage Incentive Program for Nutrition Assistance Program recipients. Funds for this program are provided by direct appropriation.

Child Nutrition Programs. The purpose of the Child Nutrition Programs -- the National School Lunch, School Breakfast, Summer Food Service and Child and Adult Care Food Programs -- is to assist State and local governments in providing food services for children in public and nonprofit private schools, child care institutions, certain adult day care centers, and summer recreation programs. FNS provides the States with cash and additional commodities on a per meal basis to offset the cost of food service and cash to offset a portion of State administrative expenses, sponsor administrative expenses and technical assistance. FNS also administers the various Child Nutrition Programs directly in cases where the State has chosen not to administer the programs. In addition to the cash and commodity assistance provided for all meals, substantially higher cash rates are paid as special assistance for meals served free or at a reduced price to children from low income families. Funds for these programs are provided by direct appropriation and by transfer from section 32.

Special Milk Program. The Special Milk Program provides funding for milk service in some kindergartens, as well as in schools, nonprofit child care centers and camps which have no other federally assisted food programs. Milk is provided to children either free or at a low cost depending on their family income level. The Food and Nutrition Service provides cash subsidies to State administered programs and directly administers the program in the States which have chosen not to administer the program. Funds for this program are provided by direct appropriation.

Special Supplemental Food Program for Women, Infants and Children (WIC). The purpose of the WIC Program is to improve the health of low-income pregnant, breastfeeding and postpartum women, infants and children up to their fifth birthday. This is achieved by providing food packages designed to supplement each participant's diet with foods that nutritional research indicates are typically lacking in the WIC target population and by providing eligible recipients with nutrition education, including information about breastfeeding, and access to health services. In addition to paying the full cost of the food packages, appropriated funds are provided to States for administrative and nutrition services costs for the program. The WIC Farmers' Market Nutrition Program (FMNP) is also funded from the WIC appropriation. The FMNP is designed to accomplish two major goals: 1) to improve the diets of WIC (or WIC-eligible) participants by providing them with coupons to purchase fresh, nutritious, unprepared foods, such as fruits

and vegetables, from farmers' markets; and 2) to increase the awareness and use of farmers' markets by low-income households. Although directly related to the WIC Program, most of the current FMNP operations are administered by State Departments of Agriculture rather than the State WIC agencies. Funds for the WIC program are provided by direct appropriation.

Commodity Supplemental Food Program (CSFP). The first priority of the CSFP is to provide food packages designed to improve the health of low-income pregnant, breastfeeding and postpartum women, infants and children up to their sixth birthday, a target population similar to that of the WIC Program. The next priority of CSFP is to provide supplemental food packages to improve the health of the low-income elderly; i.e., persons 60 years of age or older. The foods are purchased directly by the Department of Agriculture and distributed through State and local agencies to eligible women, infants, children and the elderly. The Food and Nutrition Service provides cash assistance to distributing agencies to offset their operating expenses at a rate of 20 percent of appropriated funding. Funds to purchase commodities and pay expenses for this program are provided by direct appropriation and may be supplemented by commodities purchased under farm program authorities and distributed at no charge against the funds appropriated.

Food Donations Programs for Selected Groups

Food Distribution Program on Indian Reservations (FDPIR). This program provides nutrition assistance to low-income American Indians living on or near reservations who choose not to participate in the Food Stamp Program. Through monthly distribution from local warehouses, participating Indians receive a variety of commodities to help maintain a healthy diet. Participating agencies can order food items according to households' preferences. They also receive information on proper nutrition, food storage, sanitary food preparation methods and suggestions for use of the commodities. Funds to purchase commodities and pay expenses for this program are provided by direct appropriation and may be supplemented by commodities purchased under farm program authorities and distributed at no charge against the funds appropriated.

Nutrition Program for the Elderly. This program provides cash and commodities to States for distribution to local organizations that prepare meals served to elderly persons in congregate settings or delivered to their homes. The program promotes good health through nutrition assistance and by reducing the isolation experienced by the elderly. USDA's role in this program is to supplement the Department of Health and Human Services' funding for programs for the elderly with cash and commodities on a per meal basis for each meal served to an elderly person. Funds for this program are provided by direct appropriation.

Commodities for Soup Kitchens. This program provides for the purchase and distribution of commodities to soup kitchens and food banks. Commodities are distributed to the States which, in turn, provide them to public and charitable institutions that maintain an established feeding operation to provide food to needy homeless persons on a regular basis as an integral part of their activities. In instances when these commodities cannot be used by these organizations, States provide such commodities to food banks that maintain an established operation involving the provision of food or edible commodities to food pantries, soup kitchens, hunger relief centers or other food or feeding centers that provide meals or food to needy persons on a regular basis as an integral part of their normal activities. Funds for this program are provided by direct appropriation.

The Emergency Food Assistance Program (TEFAP). The Emergency Food Assistance Program helps States to relieve situations of hunger and distress by making available surplus foods from USDA farm support program inventories. The program also provides funds to States to aid in the intrastate storage and distribution of these foods. The allocation of both commodities and administrative expense grants to the States is based on a formula which considers the States' unemployment level and the number of persons with incomes below the poverty level. Funds for this program are provided by direct appropriation.

Food Program Administration. This account funds Federal personnel compensation, benefits and other operating expenses of the Food and Nutrition Service. FNS administers the Food Stamp, Child Nutrition, Special Supplemental Food and other programs described above in a Federal-State

partnership in which State agencies and local entities directly operate most programs. FNS implements program statutes through promulgation of regulations and instructions. FNS staff provide training and assistance to State agencies, assure proper funds allocation and control, conduct program monitoring and evaluation, and develop program policy.

Agency headquarters are in Alexandria, Virginia. Regional offices are at seven locations: Boston, Massachusetts; Robbinsville, New Jersey; Atlanta, Georgia; Chicago, Illinois; Dallas, Texas; Denver, Colorado; and San Francisco, California. On September 30, 1993, FNS employed 1,819 full time permanent and 49 part time and temporary employees, of which 607 were in the headquarters office and 1,261 in the field. Of the field total, 851 employees were stationed in seven regional offices and the balance in six Food Stamp Compliance offices; one computer support center in Minneapolis, Minnesota; five Administrative Review offices; and 84 field offices. Funds for these activities are provided by direct appropriation.

Food and Nutrition Service Nutrition Education Activities

The 1995 budget request will support the FNS effort to make nutrition education an integral component of all food assistance programs as a key component of the overall initiative to update the domestic food assistance and nutrition education programs. The overall nutritional update initiative is founded in the four guiding principles: (1) implementing the Dietary Guidelines for Americans in order to promote health and prevent disease; (2) customer satisfaction; (3) flexibility; and (4) maximizing resources through cooperative efforts and partnerships.

The Food and Nutrition Service is the primary funding source for nutrition education for targeted high-risk groups. Historically, most of this funding has been used to provide nutrition education through the WIC Program to promote growth during the critical times of physical and mental development. The 1995 budget request will allow WIC nutrition education to keep pace with the overall growth of the program while increasing support for nutrition education needed to promote health through implementation of the dietary guidelines in other food assistance programs.

Dietary Guidelines Implementation in the Child Nutrition Programs

Increasing evidence on the adverse health effects of excesses in certain food components led to inclusion in the 1990 edition of the Dietary Guidelines for Americans of quantitative upper limits for fat (not more than 30% of calories) and saturated fat (less than 10% of calories). Reinforcement of the recommendation to apply these limits to the diets of children was issued by the American Academy of Pediatrics in September 1992 and by the American Dietetic Association in March 1993. The nation's Health Objectives for the Year 2000, established by the Department of Health and Human Services (HHS) with USDA concurrence on the nutrition objectives, sets out the target for this decade: "increase to at least 90 percent the proportion of school lunch and breakfast services and child care food services with menus that are consistent with the nutrition principles in the Dietary Guidelines for Americans" (Healthy People 2000, Objective 2.17, page 126). The FNS-sponsored School Nutrition Dietary Assessment Study found that in school year 1991-92, school lunches exceed dietary guidelines for fat by more than 25 percent, for saturated fat by 50 percent, and National Research Council *Diet and Health* recommendations for sodium by nearly 100 percent. It also found that children who ate the school lunch consumed a significantly higher amount of calories from fat than children who got their lunch from brown-bagging, vending machines, or elsewhere at school. Further, the report showed that virtually no schools comply with the Dietary Guidelines for Americans.

In order to implement the principles of the Dietary Guidelines during this decade to reduce the long-term disability and health-care cost of nutritionally-related chronic diseases such as coronary heart disease, stroke, diabetes, atherosclerosis, and certain types of cancer, it is necessary to improve the diets of America's children and help them establish proper eating habits for a healthy life. Therefore, the 1995 budget request provides total funding of \$32.5 million from three line items--Dietary Guidelines implementation, Nutrition Education and Training (NET) Program and the Food Service Management Institute (FSMI)--to support implementation of the Dietary Guidelines in the Child Nutrition Programs. The Dietary Guidelines implementation funding of \$20.5 million will provide FNS the flexibility to provide leadership and augment State and local efforts with specialized Dietary Guidelines menu planning guides, institutional kitchen-tested quantity recipes and training programs, and a national promotional campaign to encourage children to accept new foods and meals lower in fat, saturated fat and sodium.

Nutrition Education and Training (NET) Program

The NET program provides children, through child care and schools, with opportunities to acquire the knowledge, skills, attitudes and behaviors necessary to make healthful food choices. NET develops nutrition education programs and instructs food service workers and teachers in nutrition and health. FNS estimates that about \$10.3 million will be needed to maintain the current level of effort for NET. This NET funding is an important component of the comprehensive multi-year initiative to implement the Dietary Guidelines for Americans in the Child Nutrition Programs by the year 2000, and is needed to reach the diverse population of child care and preschool providers.

Special Supplemental Food Program for Women, Infants and Children (WIC)

WIC provides the largest single source of Federal nutrition education funding, reaching over 6 million pregnant, breastfeeding and postpartum women, infants and young children each month during critical times of physical growth and mental

development. The 1995 budget request includes funding to allow nutrition education in WIC to keep pace with program growth. A major goal of WIC nutrition education is to increase WIC breastfeeding rates. These efforts will also complement the National Healthy Objective of increasing "to at least 75 percent the proportion of mothers who breastfeed their babies at hospital discharge and to at least 50 percent the proportion who continue breastfeeding until their babies are 5 to 6 months old" (Healthy People 2000, Objective 2.11).

Food Stamp Program

The Food Stamp Program makes funding for nutrition education available to State administrative agencies at a 50:50 match rate. Historically, few States have made use of this funding, and the Federal matching share has been about \$2 million per year. Grants to promote increased nutrition education were authorized by P.L. 101-624, and were funded at \$ 0.5 million for Fiscal Year 1993. In Fiscal Year 1994, the Food Stamp Program nutrition education demonstration grants along with funds from other FNS programs were used to develop the community nutrition education challenge approach. This will foster development of community-based approaches to providing nutrition education to the target populations of the 14 FNS programs. These projects will continue in Fiscal Year 1995. The budget request for Other Program Costs includes an increase of funding which, along with retargeted funds from other Food Stamp Program research, will support up to \$ 2.75 million for broader demonstrations on integrating nutrition concepts, especially those related to the Dietary Guidelines for Americans.

Nutrition Education through the Food Distribution Program on Indian Reservations (FDPIR)

Nutrition education has traditionally been integral to FDPIR. However, past efforts in this area have proven inadequate in view of the continued high incidence of diet-related health conditions, such as hypertension, diabetes, and obesity among the Native American population. In 1994, FNS specifically earmarked some additional FDPIR administrative funds for nutrition education. The 1995 budget provides for nationwide expansion of nutrition education for FDPIR participants. These funds are allocated among regions using a participation-based formula. Regions, in turn, use their allocations for direct provision of nutrition education to Indian Tribal Organizations and their program participants, or for competitive grants to Indian Tribal Organizations. This funding is intended to stimulate and support innovative approaches to the specific nutrition education needs and cultural sensitivities of Native Americans.

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FOOD AND NUTRITION SERVICE
Available Funds and Staff-Years
1993 Actual and Estimated, 1994 and 1995

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Item	1993		1994		1995	
	Actual		Estimated		Estimated	
	Amount	Staff : Years	Amount	Staff : Years	Amount	Staff : Years
Food Stamp Program.....	27,064,357,000	25	27,045,655,000	25	27,687,710,000	35
Nutrition Assistance	[a]		[b]			
for Puerto Rico.....	1,040,175,000		1,078,528,000		1,143,000,000	
Child Nutrition Programs:						
Appropriation.....	\$2,536,098,000		\$2,727,022,000		\$2,238,533,000	
Transfer from						
Section 32.....	4,290,455,000		4,770,109,000		5,212,818,000	
Total - Child	[c]					
Nutrition Programs.....	6,826,553,000	127	7,497,131,000	127	7,451,351,000	118
	[d]		[e]		[f]	
Special Milk Program.....	14,898,000		20,277,000		18,089,000	
Special Supplemental	[g]		[h]			
Food Program.....	2,860,000,000		3,210,000,000		3,563,588,000	
Commodity Supplemental	[i]		[j]			
Food Program.....	94,500,000		104,500,000		94,500,000	
Food Donations Programs for			[k]		[l]	
Selected Groups.....	256,513,000		258,641,000		229,596,000	
Temporary Assistance.....	42,329,000		0		0	
The Emergency Food						
Assistance Program.....	165,000,000		120,230,000		40,230,000	
Food Program Administration:	103,535,000	1,764	107,767,000	1,764	106,983,000	1,757
Total, Food and Nutrition						
Service Funds.....	38,467,860,000	1,916	39,442,729,000	1,916	40,335,047,000	1,910
Obligations under other						
USDA Appropriations:						
Human Nutrition Information:						
Service for Administrative:						
Support.....	250,000	5	0		0	
Farmers Home Administration:	47,095		51,000		51,000	
Agricultural Stabilization						
and Conservation Service..	31,070		164,000	2	164,000	2
Soil Conservation Service...	12,364		0		0	
Miscellaneous Reimbursements:	304,647		96,326	1	96,326	1
Total, Other USDA						
Appropriations.....	645,176	5	311,326	3	311,326	3

FOOD AND NUTRITION SERVICE
Available Funds and Staff-Years
1993 Actual and Estimated, 1994 and 1995

Page 2 of 2

Item	1993		1994		1995	
	Actual		Estimated		Estimated	
	Amount	Staff : Years	Amount	Staff : Years	Amount	Staff : Years
Other Federal Funds:						
EBT Treasury	0		475,000	2	475,000	2
Army Audit Agency						
for Health and Building						
Management Services	7,824		10,674		10,674	
Total, Other Federal Funds...	7,824	0	485,674	2	485,674	2
Total, Food and						
Nutrition Service.....	38,468,513,000	1,921	39,443,526,000	1,921	40,335,844,000	1,915

[a] Excludes \$10,825,000 in funds transferred to APHIS for Tick Eradication.

[b] Excludes \$12,472,000 in funds transferred to APHIS for Tick Eradication.

[c] Excludes \$26,767,817 in unobligated balances and \$56,450,674 in recoveries of PY obligations.

[d] Excludes \$5,379,187 in unobligated balances and \$1,377,812 in recoveries of PY obligations.

[e] Excludes \$347,680 in unobligated balances.

[f] Excludes \$1,633,680 in unobligated balances.

[g] Excludes \$2,647,148 in unobligated balances and \$66,641,958 in recoveries of PY obligations.

[h] Excludes \$288,982 in unobligated balances.

[i] Excludes \$2,876,767 in recoveries of PY obligations.

[j] Excludes \$12,280,664 in unobligated balances proposed for rescission.

[k] Excludes \$6,060,832 in unobligated balances.

[l] Excludes \$31,163,000 in unobligated balances.

Permanent Positions by Grade and Staff-Year Summary

1993 and Estimated 1994 and 1995

	1993			1994			1995		
	Headquarters	Field	Total	Headquarters	Field	Total	Headquarters	Field	Total
ES-6	0	0	0	0	0	0	0	0	0
ES-5	1	0	1	1	0	1	1	0	1
ES-4	3	6	9	3	5	8	3	6	9
ES-3	1	1	2	1	1	2	1	1	2
ES-2	1	0	1	1	0	1	1	0	1
ES-1	2	0	2	2	0	2	2	0	2
GS/GM-15	21	7	28	19	7	26	19	7	26
GS/GM-14	44	35	79	44	35	79	44	35	79
GS/GM-13	129	80	209	135	82	217	132	79	211
GS-12	137	268	405	139	270	409	138	266	404
GS-11	126	526	652	127	547	674	127	540	667
GS-10	1	0	1	1	0	1	1	0	1
GS-9	30	75	105	31	85	116	29	79	108
GS-8	6	7	13	6	7	13	6	7	13
GS-7	39	67	106	41	72	113	38	65	103
GS-6	30	60	90	30	60	90	30	55	85
GS-5	28	119	147	29	128	157	29	119	148
GS-4	15	29	44	15	30	45	15	27	42
GS-3	4	5	9	4	5	9	4	4	8
GS-2	1	2	3	1	2	3	1	0	1
GS-1	0	0	0	0	0	0	0	0	0
Ungraded Positions	4	0	4	4	0	4	4	0	4
Total Permanent Positions	623	1,287	1,910	634	1,336	1,970	625	1,290	1,915
Unfilled Positions end-of-year	-16	-26	-42	-3	-25	-28	-5	-11	-16
Total, Permanent Employment, end-of-year	607	1,261	1,868	631	1,311	1,942	620	1,279	1,899
Staff-Years	614	1,307	1,921	656	1,265	1,921	639	1,276	1,915

FOOD AND NUTRITION SERVICE

CLASSIFICATION BY OBJECTS

(dollars in thousands)

	Actual 1993	Estimated 1994	Estimated 1995
Personnel Compensation:			
Headquarters	32,144	33,000	33,532
Field	48,503	49,377	52,615

11 Total personnel compensation	80,647	82,377	86,147
11.1 Full-time permanent	77,569	79,040	83,183
11.3 Other than full-time permanent	2,192	2,614	2,084
11.9 Special personal services	886	723	880
12 Personnel benefits	14,737	15,003	14,827
13 Benefits for former personnel	53	44	42

Total pers. compensation and benefits	95,437	97,424	101,016
Other objects:			
21 Travel	3,877	4,393	4,567
22 Transportation of things	4,881	5,403	5,492
23.1 Rental payments to GSA			
23.2 Rental payments to others	234	425	423
23.3 Communications, utilities and misc. charges	3,231	3,509	2,790
24 Printing and reproduction	24,140	50,031	52,073
25.1 Consulting services	48,480	64,214	64,052
25.2 Other services	6,435	8,181	7,252
26 Supplies and materials (incl. commodities)	544,808	468,161	440,651
31 Equipment	1,875	1,684	1,728
32 Land and structures			
41 Grants, subsidies and contributions	34,402,014	35,801,907	37,631,066
42 Insurance claims and indemnities	200		
43 Interest and dividends			

Total other objects	35,040,175	36,407,908	38,210,094

Total direct obligations	35,135,612	36,505,332	38,311,110
=====			
Position Data:			
Average Salary, ES positions	104,287	108,698	113,296
Average Salary, GM/GS positions	40,676	43,278	45,864
Average Grade, GM/GS positions	10.24	10.36	10.36

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FOOD AND NUTRITION SERVICE

Reports of Audits and Investigations of National Significance
Received during Fiscal Year 1993

<u>Program/Activity Reviews</u>	<u>Report Number</u>	<u>Date Issued</u>	<u>Subject</u>
<u>Reports from the Office of the Inspector General</u>			
Food Distribution	50600-8-CH	12/28/92	Quality of Audits Performed on Multi-State Food Processors by Certified Public Accountants
Child Nutrition	27099-2-KC	08/04/93	Effectiveness of Single Audits, Child Nutrition Programs
Food Stamps	27019-24-HY	09/02/92	Compliance Branch Controls over Cash and Food Stamp Coupon Inventories
Food Stamps	27019-72-CH	09/30/93	Eligibility of Convenience Stores
Financial Management	27070-4-HY	03/23/93	Issues Identified during FY 1991 Financial Statements Requiring Management Action
Financial Management	27070-4-HY	08/20/93	Financial Statements FY 1992
<u>Reports from the General Accounting Office</u>			
Child Nutrition	RCED-93-5	10/16/92	Food Assistance: School Milk Contract Bid-Rigging
Food Stamps	RCED-93-70R	11/25/92	Food Stamp Program Provisions

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FOOD AND NUTRITION SERVICE

Food Assistance Table
 Budget Authority - Current Law/Recommended Level
 (Dollars in Thousands)

	1993 Actual	1994 Estimate	1995 Estimate	Change 1994-1995
A. Child Nutrition Programs:				
1. Program grants to States:				
a. School Lunch Program.....	4,149,236	4,503,445	4,134,766	-368,679
b. School Breakfast Program.....	899,178	950,385	1,027,230	76,845
c. Child Care and Adult Care Food Program.....	1,221,173	1,467,836	1,643,448	175,612
d. Summer Food Service Program.....	228,006	232,891	256,564	23,673
e. State administrative expenses.....	77,086	85,832	94,041	8,209
TOTAL, Cash payments to States.....	6,574,679	7,240,389	7,156,049	-84,340
2. Commodities to States (including cash in lieu of commodities):				
a. FMS commodities.....	230,598	234,881	255,317	20,436
b. AMS Section 32 commodities.....	400,000	400,000	400,000	0
c. CCC bonus commodities.....	0	0	0	0
d. AMS bonus commodities.....	0	0	0	0
TOTAL, Commodities to States.....	630,598	634,881	655,317	20,436
3. Nutrition studies and education:				
a. Nutrition studies and surveys, section 6(a)(3)..	3,835	3,835	3,663	-172
b. Nutrition education and training, section 19....	10,000	10,270	10,270	0
c. Child Nutrition Coordinated Review System.....	3,780	3,849	3,849	0
d. Food Service Management Institute.....	1,661	1,853	1,706	-147
e. Dietary Guidelines.....	2,000	2,054	20,497	18,443
TOTAL, Nutrition studies and education.....	21,276	21,861	39,985	18,124
Section 17(p) Demos.....	0	0	0	0
TOTAL, Child Nutrition Programs.....	7,226,553	7,897,131	7,851,351	-45,780
LESS: AMS Section 32 commodities.....	400,000	400,000	400,000	0
CCC bonus commodities.....	0	0	0	0
AMS bonus commodities.....	0	0	0	0
TOTAL, FMS Child Nutrition Account.....	6,826,553	7,497,131	7,451,351	-45,780
B. Special Milk Program: Cash Payments.....	14,898	20,277	18,089	-2,188
C. Special Supplemental Food Program (WIC):				
1. Cash grants to States.....	2,855,000	3,205,000	3,560,093	355,093
2. Studies and evaluations.....	5,000	5,000	3,495	-1,505
TOTAL, FMS Special Supplemental Food Program Account.....	2,860,000	3,210,000	3,563,588	353,588

Continued on next page

FOOD AND NUTRITION SERVICE

Food Assistance Table

Budget Authority - Current Law/Recommended Level
(Dollars in Thousands)

	1993 Actual	1994 Estimate	1995 Estimate	Change 1994-1995
D. Commodity Supplemental Food Program (CSFP):				
1. Commodities for supplemental food.....	75,600	83,600	75,600	-8,000
2. Payments to distributing agencies for administration.....	18,900	20,900	18,900	-2,000
3. CCC donations.....	0	0	0	0
SUBTOTAL, Commodity Supplemental Food Program (CSFP)...	94,500	104,500	94,500	-10,000
LESS: CCC Donations.....	0	0	0	0
TOTAL, FNS CSFP Account.....	94,500	104,500	94,500	-10,000
E. Food Stamp Program:				
1. Benefit costs.....	22,840,989	22,826,031	23,466,298	640,267
2. State administrative costs.....	1,630,226	1,614,079	1,631,225	17,146
3. Other program costs.....	93,142	106,545	111,787	5,242
4. Benefit Reserve.....	2,500,000	2,500,000	2,500,000	0
5. Excess state error liabilities.....	0	-1,000	0	1,000
6. Fed. Tax Refund Program.....	0	0	-21,600	-21,600
7. Adjustments in expired accounts.....	0	0	0	0
8. Unobligated balance expiring.....	0	0	0	0
TOTAL, FNS Food Stamp Program Account.....	27,064,357	27,045,655	27,687,710	642,055
F. Nutrition Assistance for Puerto Rico.....				
	1,051,000	1,091,000	1,143,000	52,000
G. Food Donations Programs:				
1. Food Distribution Program on Indian Reservations:				
a. Commodities in lieu of food stamps.....	54,405	49,736	18,107	-31,629
b. Distributing agency administrative costs.....	18,444	18,905	20,347	1,442
c. Section 32 bonus commodities.....	0	0	0	0
d. Section 416 bonus commodities.....	0	0	0	0
TOTAL, Food Distribution Program on Reservations.....	72,849	68,641	38,454	-30,187
LESS: Bonus commodities.....	0	0	0	0
TOTAL, FNS Food Distribution Program on Indian Reservations Account.....	72,849	68,641	38,454	-30,187
2. Nutrition Program for the Elderly:				
a. Commodities.....	9,367	9,828	9,263	-565
b. Cash in lieu of commodities.....	142,297	140,172	131,879	-8,293
c. Section 32 Bonus Commodities.....	0	0	0	0
d. Section 416 Bonus Commodities.....	0	0	0	0
TOTAL, Nutrition Program for the Elderly.....	151,664	150,000	141,142	-8,858
LESS: Bonus Commodities.....	0	0	0	0
TOTAL, FNS Nutrition Program for the Elderly Account.....	151,664	150,000	141,142	-8,858
3. Commodities for Soup Kitchens.....	32,000	40,000	50,000	10,000
TOTAL, FNS Food Donations Programs Account.....	256,513	258,641	229,596	-29,045

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FOOD AND NUTRITION SERVICE

Food Assistance Table
 Budget Authority - Current Law/Recommended Level
 (Dollars in Thousands)

	1993 Actual	1994 Estimate	1995 Estimate	Change 1994-1995
<hr/>				
H. The Emergency Food Assistance Program (TEFAP):				
1. FMS Commodities.....	120,000	80,220	220	-80,000
2. CCC Bonus Commodities.....	0	0	0	0
3. TEFAP Administrative Expense.....	45,000	40,010	40,010	0
TOTAL, The Emergency Food Assistance Program.....	165,000	120,230	40,230	-80,000
LESS: Bonus Commodities.....	0	0	0	0
TOTAL, FMS TEFAP Account.....	165,000	120,230	40,230	-80,000
<hr/>				
I. Temporary Assistance P.L. 102-552: Commodities.....	42,329	0	0	0
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J. Bonus Commodities to Other Outlets:				
1. Charitable Institutions				
a. Section 32 commodities.....	0	0	0	0
b. Section 416 commodities.....	0	0	0	0
2. Summer Camps				
a. Section 32 commodities.....	0	0	0	0
b. Section 416 commodities.....	0	0	0	0
3. Disaster Feeding				
a. Section 32 commodities.....	0	0	0	0
b. Section 416 commodities.....	0	0	0	0
TOTAL, Bonus Commodities to Other Outlets.....	0	0	0	0
<hr/>				
K. Food Program Administration:				
1. Child nutrition/Special Milk.....	27,414	28,516	28,303	-213
2. Supplemental feeding.....	11,409	11,875	11,789	-86
3. Food stamp.....	57,952	60,319	59,886	-433
4. Cash and commodity subsidies.....	6,760	7,057	7,005	-52
TOTAL, Food Program Administration.....	103,535	107,767	106,983	-784
<hr/>				
GRAND TOTAL, Food Assistance.....	38,878,685	39,855,201	40,735,047	879,846
<hr/>				
LESS: Section 32 commodities for Child Nutrition.....	400,000	400,000	400,000	0
AMS bonus commodities.....	0	0	0	0
CCC bonus commodities.....	0	0	0	0
TOTAL, FMS Accounts.....	38,478,685	39,455,201	40,335,047	879,846
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FOOD AND NUTRITION SERVICE

Food Assistance Table

Program Level - Current Law/Recommended Level
(Dollars in Thousands)

	1993 Actual	1994 Estimate	1995 Estimate	Change 1994-1995
A. Child Nutrition Programs:				
1. Program grants to States:				
a. School Lunch Program.....	4,129,944	4,271,896	4,436,432	164,536
b. School Breakfast Program.....	899,178	950,385	1,027,230	76,845
c. Child Care and Adult Care Food Program.....	1,221,174	1,467,836	1,643,448	175,612
d. Summer Food Service Program.....	228,006	232,891	256,564	23,673
e. State administrative expenses.....	78,476	89,449	94,041	4,592
TOTAL, Cash payments to States.....	6,556,778	7,012,457	7,457,715	445,258
2. Commodities to States (including cash in lieu of commodities):				
a. FNS commodities.....	230,598	234,881	255,317	20,436
b. AMS Section 32 commodities.....	389,900	400,000	400,000	0
c. CCC bonus commodities.....	50,797	50,797	50,797	0
d. AMS bonus commodities.....	39,367	39,367	39,367	0
TOTAL, Commodities to States.....	710,662	725,045	745,481	20,436
3. Nutrition studies and education:				
a. Nutrition studies and surveys, section 6(a)(3)...	3,835	3,835	3,663	-172
b. Nutrition education and training, section 19....	10,000	10,270	10,270	0
c. Child Nutrition Coordinated Review System.....	4,017	3,849	3,849	0
d. Food Service Management Institute.....	1,661	1,853	1,706	-147
e. Dietary Guidelines.....	450	3,604	20,497	16,893
TOTAL, Nutrition studies and education.....	19,963	23,411	39,985	16,574
Section 17(p) Demos.....	0	0	0	0
TOTAL, Child Nutrition Programs.....	7,287,403	7,760,913	8,243,181	482,268
LESS: AMS Section 32 commodities.....	389,900	400,000	400,000	0
CCC bonus commodities.....	50,797	50,797	50,797	0
AMS bonus commodities.....	39,367	39,367	39,367	0
TOTAL, FNS Child Nutrition Account.....	6,807,339	7,270,749	7,753,017	482,268
B. Special Milk Program: Cash Payments.....	19,109	18,991	19,723	732
C. Special Supplemental Food Program (WIC):				
1. Cash grants to States.....	2,923,492	3,325,289	3,680,093	354,804
2. Studies and evaluations.....	4,711	5,000	3,495	-1,505
TOTAL, FNS Special Supplemental Food Program Account.....	2,928,203	3,330,289	3,683,588	353,299

Continued on next page

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FOOD AND NUTRITION SERVICE

Food Assistance Table
 Program Level - Current Law/Recommended Level
 (Dollars in Thousands)

	1993	1994	1995	Change
	Actual	Estimate	Estimate	1994-1995
<hr/>				
D. Commodity Supplemental Food Program (CSFP):				
1. Commodities for supplemental food.....	63,321	83,600	75,600	-8,000
2. Payments to distributing agencies for administration.....	19,013	20,900	18,900	-2,000
3. CCC donations.....	20,927	32,996	22,535	-10,461
SUBTOTAL, Commodity Supplemental Food Program (CSFP).. <td>103,261</td> <td>137,496</td> <td>117,035</td> <td>-20,461</td>	103,261	137,496	117,035	-20,461
LESS: CCC Donations.....	20,927	32,996	22,535	-10,461
TOTAL, FNS CSFP Account.....	82,334	104,500	94,500	-10,000
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E. Food Stamp Program:				
1. Benefit costs.....	22,010,475	22,520,115	23,466,298	946,183
2. State administrative costs.....	1,618,821	1,614,079	1,631,225	17,146
3. Other program costs.....	68,361	106,545	111,787	5,242
4. Benefit Reserve.....	0	0	0	0
5. Excess state error liabilities.....	0	0	0	0
6. Fed. Tax Refund Program.....	0	0	0	0
7. Adjustments in expired accounts.....	0	0	0	0
8. Unobligated balance expiring.....	0	0	0	0
TOTAL, FNS Food Stamp Program Account.....	23,697,657	24,240,739	25,209,310	968,571
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F. Nutrition Assistance for Puerto Rico.....	1,040,175	1,078,528	1,143,000	64,472
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G. Food Donations Programs:				
1. Food Distribution Program on Indian Reservations:				
a. Commodities in lieu of food stamps.....	49,644	24,634	49,270	24,636
b. Distributing agency administrative costs.....	18,143	18,905	20,347	1,442
c. Section 32 bonus commodities.....	0	0	0	0
d. Section 416 bonus commodities.....	1,393	1,393	1,393	0
TOTAL, Food Distribution Program on Reservations.....	69,180	44,932	71,010	26,078
LESS: Bonus commodities.....	1,393	1,393	1,393	0
TOTAL, FNS Food Distribution Program on Indian Reservations Account.....	67,787	43,539	69,617	26,078
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2. Nutrition Program for the Elderly:				
a. Commodities.....	8,074	9,828	9,263	-565
b. Cash in lieu of commodities.....	142,591	140,172	131,879	-8,293
c. Section 32 Bonus Commodities.....	535	535	535	0
d. Section 416 Bonus Commodities.....	263	263	263	0
TOTAL, Nutrition Program for the Elderly.....	151,463	150,798	141,940	-8,858
LESS: Bonus Commodities.....	798	798	798	0
TOTAL, FNS Nutrition Program for the Elderly Account.....	150,665	150,000	141,142	-8,858
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3. Commodities for Soup Kitchens.....	32,000	40,000	50,000	10,000
TOTAL, FNS Food Donations Programs Account.....	250,452	233,539	260,759	27,220
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FOOD AND NUTRITION SERVICE

Food Assistance Table

Program Level - Current Law/Recommended Level
(Dollars in Thousands)

	1993 Actual	1994 Estimate	1995 Estimate	Change 1994-1995
<hr/>				
H. The Emergency Food Assistance Program (TEFAP):				
1. FNS Commodities.....	120,000	80,220	220	-80,000
2. CCC Bonus Commodities.....	63,325	63,325	63,325	0
3. TEFAP Administrative Expense.....	44,987	40,010	40,010	0
TOTAL, The Emergency Food Assistance Program.....	228,312	183,555	103,555	-80,000
LESS: Bonus Commodities.....	63,325	63,325	63,325	0
TOTAL, FNS TEFAP Account.....	164,987	120,230	40,230	-80,000
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I. Temporary Assistance P.L. 102-552: Commodities.....	42,329	0	0	0
<hr/>				
J. Bonus Commodities to Other Outlets:				
1. Charitable Institutions				
a. Section 32 commodities.....	10,764	10,764	10,764	0
b. Section 416 commodities.....	84,660	84,660	84,660	0
2. Summer Camps				
a. Section 32 commodities.....	260	260	260	0
b. Section 416 commodities.....	3,246	3,246	3,246	0
3. Disaster Feeding				
a. Section 32 commodities.....	1,991	1,991	1,991	0
b. Section 416 commodities.....	230	230	230	0
TOTAL, Bonus Commodities to Other Outlets.....	101,151	101,151	101,151	0
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K. Food Program Administration:				
1. Child nutrition/Special Milk.....	27,289	28,516	28,303	-213
2. Supplemental feeding.....	11,117	11,875	11,789	-86
3. Food stamp.....	57,987	60,319	59,886	-433
4. Cash and commodity subsidies.....	6,634	7,057	7,005	-52
TOTAL, Food Program Administration.....	103,027	107,767	106,983	-784
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GRAND TOTAL, Food Assistance.....	35,803,270	37,195,159	38,990,476	1,795,317
<hr/>				
LESS: Section 32 commodities for Child Nutrition.....	389,900	400,000	400,000	0
AMS bonus commodities.....	52,917	52,917	52,917	0
CCC bonus commodities.....	224,841	236,910	226,449	-10,461
TOTAL, FNS Accounts.....	35,135,612	36,505,332	38,311,110	1,805,778
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FOOD AND NUTRITION SERVICE

Food Assistance Table
 Outlays - Current Law/Recommended Level
 (Dollars in Thousands)

	1993 Actual	1994 Estimate	1995 Estimate	Change 1994-1995
A. Child Nutrition Programs:				
1. Program grants to States:				
a. School Lunch Program.....	3,954,668	4,266,857	4,412,410	145,553
b. School Breakfast Program.....	885,379	949,109	1,016,011	66,902
c. Child Care and Adult Care Food Program.....	1,202,320	1,440,111	1,617,809	177,698
d. Summer Food Service Program.....	228,283	238,169	253,108	14,939
e. State administrative expenses.....	75,377	84,116	92,572	8,456
TOTAL, Cash payments to States.....	6,346,027	6,978,362	7,391,910	413,548
2. Commodities to States (including cash in lieu of commodities):				
a. FNS commodities.....	230,598	234,881	255,317	20,436
b. AMS Section 32 commodities.....	389,900	400,000	400,000	0
c. CCC bonus commodities.....	0	0	0	0
d. AMS bonus commodities.....	0	0	0	0
TOTAL, Commodities to States.....	620,498	634,881	655,317	20,436
3. Nutrition studies and education:				
a. Nutrition studies and surveys, section 6(a)(3)..	3,835	3,835	3,663	-172
b. Nutrition education and training, section 19....	10,000	10,270	10,270	0
c. Child Nutrition Coordinated Review System.....	4,017	3,849	3,849	0
d. Food Service Management Institute.....	1,661	1,853	1,706	-147
e. Dietary Guidelines.....	450	3,604	20,497	16,893
TOTAL, Nutrition studies and education.....	19,963	23,411	39,985	16,574
Section 17(p) Demos.....	0	0	0	0
TOTAL, Child Nutrition Programs.....	6,986,488	7,636,654	8,087,212	450,558
LESS: AMS Section 32 commodities.....	389,900	400,000	400,000	0
CCC bonus commodities.....	0	0	0	0
AMS bonus commodities.....	0	0	0	0
TOTAL, FNS Child Nutrition Account.....	6,596,588	7,236,654	7,687,212	450,558
B. Special Milk Program: Cash Payments.....	15,535	21,370	19,547	-1,823
C. Special Supplemental Food Program (WIC):				
1. Cash grants to States.....	2,842,499	3,213,021	3,534,193	321,172
2. Studies and evaluations.....	3,989	9,129	3,604	-5,525
TOTAL, FNS Special Supplemental Food Program Account.....	2,846,488	3,222,150	3,537,797	315,647

Continued on next page

FOOD AND NUTRITION SERVICE

Food Assistance Table
Outlays - Current Law/Recommended Level
(Dollars in Thousands)

	1993 Actual	1994 Estimate	1995 Estimate	Change 1994-1995
<hr/>				
D. Commodity Supplemental Food Program (CSFP):				
1. Commodities for supplemental food.....	56,970	84,362	75,936	-8,426
2. Payments to distributing agencies for administration.....	20,353	22,531	18,984	-3,547
3. CCC donations.....	0	0	0	0
SUBTOTAL, Commodity Supplemental Food Program (CSFP).. <td>77,323</td> <td>106,893</td> <td>94,920</td> <td>-11,973</td>	77,323	106,893	94,920	-11,973
LESS: CCC Donations.....	0	0	0	0
TOTAL, FNS CSFP Account.....	77,323	106,893	94,920	-11,973
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E. Food Stamp Program:				
1. Benefit costs.....	21,897,116	23,914,850	23,464,595	-450,255
2. State administrative costs.....	1,585,884	1,539,259	1,620,439	81,180
3. Other program costs.....	94,380	93,652	118,375	24,723
4. Benefit Reserve.....	0	0	0	0
5. Excess state error liabilities.....	0	-1,000	0	1,000
6. Fed. Tax Refund Program.....	0	0	-21,600	-21,600
7. Adjustments in expired accounts.....	0	0	0	0
8. Unobligated balance expiring.....	0	0	0	0
TOTAL, FNS Food Stamp Program Account.....	23,577,380	25,546,761	25,181,809	-364,952
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F. Nutrition Assistance for Puerto Rico.....	1,025,051	1,077,629	1,141,447	63,818
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G. Food Donations Programs:				
1. Food Distribution Program on Indian Reservations:				
a. Commodities in lieu of food stamps.....	59,757	21,280	44,589	23,309
b. Distributing agency administrative costs.....	18,171	18,571	20,073	1,502
c. Section 32 bonus commodities.....	0	0	0	0
d. Section 416 bonus commodities.....	0	0	0	0
TOTAL, Food Distribution Program on Reservations.....	77,928	39,851	64,662	24,811
LESS: Bonus commodities.....	0	0	0	0
TOTAL, FNS Food Distribution Program on Indian Reservations Account.....	77,928	39,851	64,662	24,811
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2. Nutrition Program for the Elderly:				
a. Commodities.....	8,032	8,003	9,371	1,368
b. Cash in lieu of commodities.....	131,693	165,121	133,454	-31,667
c. Section 32 Bonus Commodities.....	0	0	0	0
d. Section 416 Bonus Commodities.....	0	0	0	0
TOTAL, Nutrition Program for the Elderly.....	139,725	173,124	142,825	-30,299
LESS: Bonus Commodities.....	0	0	0	0
TOTAL, FNS Nutrition Program for the Elderly Account.....	139,725	173,124	142,825	-30,299
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3. Commodities for Soup Kitchens.....	30,433	41,567	50,000	8,433
TOTAL, FNS Food Donations Programs Account.....	248,086	254,542	257,487	2,945

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FOOD AND NUTRITION SERVICE

Food Assistance Table
 Outlays - Current Law/Recommended Level
 (Dollars in Thousands)

	1993 Actual	1994 Estimate	1995 Estimate	Change 1994-1995
<hr/>				
H. The Emergency Food Assistance Program (TEFAP):				
1. FNS Commodities.....	120,000	80,220	220	-80,000
2. CCC Bonus Commodities.....	0	0	0	0
3. TEFAP Administrative Expense.....	43,386	43,477	40,010	-3,467
TOTAL, The Emergency Food Assistance Program.....	163,386	123,697	40,230	-83,467
LESS: Bonus Commodities.....	0	0	0	0
TOTAL, FNS TEFAP Account.....	163,386	123,697	40,230	-83,467
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I. Temporary Assistance P.L. 102-552: Commodities.....	42,329	0	0	0
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J. Bonus Commodities to Other Outlets:				
1. Charitable Institutions				
a. Section 32 commodities.....	0	0	0	0
b. Section 416 commodities.....	0	0	0	0
2. Summer Camps				
a. Section 32 commodities.....	0	0	0	0
b. Section 416 commodities.....	0	0	0	0
3. Disaster Feeding				
a. Section 32 commodities.....	0	0	0	0
b. Section 416 commodities.....	0	0	0	0
TOTAL, Bonus Commodities to Other Outlets.....	0	0	0	0
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K. Food Program Administration:				
1. Child nutrition/Special Milk.....	30,191	29,052	28,037	-1,015
2. Supplemental feeding.....	13,802	13,437	11,512	-1,925
3. Food stamp.....	56,836	58,179	59,612	1,433
4. Cash and commodity subsidies.....	7,041	6,770	6,778	8
TOTAL, Food Program Administration.....	107,870	107,438	105,939	-1,499
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GRAND TOTAL, Food Assistance.....	35,089,936	38,097,134	38,466,388	369,254
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LESS: Section 32 commodities for Child Nutrition.....	389,900	400,000	400,000	0
AMS bonus commodities.....	0	0	0	0
CCC bonus commodities.....	0	0	0	0
TOTAL, FNS Accounts.....	34,700,036	37,697,134	38,066,388	369,254
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FOOD AND NUTRITION SERVICE

The estimate includes appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

State Child Nutrition Payments (Including Transfers of Funds):

- 1 For necessary expenses to carry out the National School Lunch Act (42 U.S.C. 1751-1769b), and the applicable provisions other than sections 3 and 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1773-1785, and 1788-1789);
- 2 [\$7,497,131,000] \$7,451,351,000 to remain available through September 30, [1995] 1996, of which [\$2,727,022,000] \$2,238,533,000 is hereby appropriated and [\$4,770,109,000] \$5,212,818,000 shall be derived by transfer from funds available under section 32 of the Act of August 24, 1935 (7 U.S.C. 612c), including \$50,000,000 from funds directed by P.L. 103-111 to uses authorized by section 1541 of section 301(b) of P.L. 100-387 as amended: Provided, That funds appropriated for the purpose of section 7 of the Child Nutrition Act of 1966 shall be allocated among the States but the distribution of such funds to an individual State is contingent upon that State's agreement to participate in studies and surveys of programs authorized under the National School Lunch Act and the Child Nutrition Act of 1966, when such studies and surveys have been directed by the Congress and requested by the Secretary of Agriculture: Provided further, That if the Secretary of Agriculture determines that a State's administration of any program under the National School Lunch Act or the Child Nutrition Act of 1966 (other than section 17), or the regulations issued pursuant to these Acts, is seriously deficient, and the State fails to correct the deficiency within a specified period of time, the Secretary may withhold from the State some or all of the funds allocated to the State under section 7 of the Child Nutrition Act of 1966 and under section 13(k)(1) of the National School Lunch Act; upon a subsequent determination by the Secretary that the programs are operated in an acceptable manner some or all of the funds withheld may be allocated: Provided further, That only final reimbursement claims for service of meals, supplements, and milk submitted to State agencies by eligible schools, summer camps, institutions, and service institutions within sixty days following the month for which the reimbursement is claimed shall be eligible for reimbursement from funds appropriated under this Act. States may receive program funds appropriated under this Act for meals, supplements, and milk served during any month only if the final program operations report for such month is submitted to the Department within ninety days following that month. Exceptions to these claims or reports submission requirements may be made at the discretion of the Secretary: Provided further, That up to \$3,849,000 shall be available for independent verification of school food service claims: Provided further, That [\$1,853,000] \$1,706,000 shall be available to provide financial and other assistance to operate the Food Service Management Institute.

The first change makes funds provided available through September 30, 1996.

The second change makes available \$50.0 million from section 32 that was appropriated for the promotion of sunflower and cottonseed oil in P.L. 103-111.

CHILD NUTRITION PROGRAMS

Appropriations Act, 1994.....	\$7,497,131,000
Budget Request, 1995.....	<u>7,451,351,000</u>
Decrease in Appropriations.....	<u>-45,780,000</u>

SUMMARY OF INCREASES AND DECREASES
(On basis of appropriation)

<u>Item of Change</u>	<u>1994 Estimated</u>	<u>Pay Cost</u>	<u>Program Changes</u>	<u>1995 Estimated</u>
School lunch program...	\$4,503,445,000	--	-\$368,679,000	\$4,134,766,000
School breakfast pgm...	950,385,000	--	+76,845,000	1,027,230,000
Child and adult care food program.....	1,467,836,000	--	+175,612,000	1,643,448,000
Summer food service program.....	232,891,000	+20,000	+23,653,000	256,564,000
State administrative expenses.....	85,832,000	+18,000	+8,191,000	94,041,000
Commod. procurement & Coordinated Review Effort	234,881,000		+20,436,000	255,317,000
	3,849,000	+36,000	-36,000	3,849,000
Nutrition studies and surveys.....	3,835,000	--	-172,000	3,663,000
Nutrition education and training.....	10,270,000	--	-0-	10,270,000
Food Service Management Institute.....	1,853,000	--	-147,000	1,706,000
Dietary Guidelines....	<u>2,054,000</u>	--	<u>+18,443,000</u>	<u>20,497,000</u>
Total Appropriation...	7,497,131,000	+74,000	-45,854,000	7,451,351,000

a/ In addition, \$400.0 million in commodities is available from section 32.

PROJECT STATEMENT
(On basis of appropriation)

<u>Project</u>	<u>1993 Actual Amount</u>	<u>1994 Estimated Amount</u>	<u>Increase or Decrease</u>	<u>1995 Estimated Amount</u>
1. Cash payments:				
to States :				
(a) School lunch:				
(1) Above 185% :				
of poverty: \$337,085,000:		\$369,239,000:	-\$30,188,000:	\$339,051,000:
(2) 130-185% :				
of poverty: 390,526,000:		427,777,000:	-34,975,000:	392,802,000:
(3) Below 130% :				
of poverty: <u>3,421,625,000:</u>		<u>3,706,429,000:</u>	<u>-\$303,516,000:</u>	<u>3,402,913,000:</u>
Total, School :			(2):	
Lunch.....: 4,149,236,000:		4,503,445,000:	-\$368,679,000:	4,134,766,000:
(b) School :				
Breakfast :				
program.... :				
(1) Above 185% :				
of poverty: 21,580,000:		22,809,000:	+1,845,000:	24,654,000:
(2) 130-185% :				
of poverty: 36,866,000:		38,966,000:	+3,150,000:	42,116,000:
(3) Below 130% :				
of poverty: <u>840,732,000:</u>		<u>888,610,000:</u>	<u>+71,850,000:</u>	<u>960,460,000:</u>
Total, School :			(3):	
Breakfast.....: 899,178,000:		950,385,000:	+76,845,000:	1,027,230,000:
(c) CACFP :				
(1) Meal :				
Service: :				
(a) Above 185% :				
of poverty: 524,403,000:		608,624,000:	+88,060,000:	696,684,000:
(b) 130-185% :				
of poverty: 37,371,000:		47,240,000:	+3,943,000:	51,183,000:
(c) Below 130% :				
poverty: <u>643,750,000:</u>		<u>790,411,000:</u>	<u>+81,194,000:</u>	<u>871,605,000:</u>
Subtotal.....: <u>1,205,524,000:</u>		<u>1,446,275,000:</u>	<u>+173,197,000:</u>	<u>1,619,472,000:</u>
(2) Audit :				
expense.....: <u>15,649,000:</u>		<u>21,561,000:</u>	<u>+2,415,000:</u>	<u>23,976,000:</u>

PROJECT STATEMENT
(On basis of appropriation)

Project	1993 Actual Amount	Sys	1994 Estimated Amount	Sys	Increase or Decrease	1995 Estimated Amount	Sys
Total, Child and Adult Care:					(4):		
Food Program...	1,221,173,000:		1,467,836,000:		+175,612,000:	1,643,448,000:	
(d) Summer Food:					(1) (5):		
Svc Program:	228,006,000:	35:	232,891,000:	40:	+23,673,000:	256,564,000:	37
(e) State Admin. expenses....	77,086,000:	30:	85,832,000:	15:	+8,209,000:	94,041,000:	15
2. Commodity Procurement:							
(a) Commodities:	183,950,800:		187,435,000:		+16,308,000:	203,743,000:	
(b) Cash-in-lieu of commodities:	46,647,200:		47,446,000:		+4,128,000:	51,574,000:	
Total, Commodity procurement. 1/:	230,598,000:		234,881,000:		+20,436,000:	255,317,000:	
3. Coordinated Review.. 1/...	3,780,000:	62:	3,849,000:	72:	-0-:	3,849,000:	66
4. Nutrition Studies and Education:							
(a) Nutrition Studies and Surveys.....	3,835,000:		3,835,000:		-172,000:	3,663,000:	
(b) Nutrition Ed. and training:	10,000,000:		10,270,000:		-0-:	10,270,000:	
(c) Food Service Management Institute....	1,661,000:		1,853,000:		-147,000:	1,706,000:	
(d) Dietary Guidelines..	2,000,000:		2,054,000:		+18,443,000:	20,497,000:	
Total, Nutrition Studies and Education. 1/...	17,496,000:		18,012,000:		+18,124,000:	36,136,000:	
Total, Available or Estimate..	6,826,553,000:	127:	7,497,131,000:	127:	-45,780,000:	7,451,351,000:	118

PROJECT STATEMENT
(On basis of available funds)

Project	1993 Actual Amount	Sys	1994 Estimated Amount	Sys	Increase or Decrease	1995 Estimated Amount	Sys
1. Cash payments to States:							
(a) School lunch:							
(1) Above 185% of poverty:	\$338,655,000:		\$350,252,000:		+\$13,535,000:	\$363,787,000:	
(2) 130-185% of poverty:	392,345,000:		405,780,000:		+15,681,000:	421,461,000:	
(3) Below 130% of poverty:	3,398,943,939:		3,515,864,000:		+135,319,237:	3,651,183,716:	
Total, School Lunch.....	4,129,943,939:		4,271,896,000:		+164,535,237:	4,436,431,716:	
(b) School Breakfast program....							
(1) Above 185% of poverty:	21,580,000:		22,809,000:		+1,845,000:	24,654,000:	
(2) 130-185% of poverty:	36,866,000:		38,966,000:		+3,150,000:	42,116,000:	
(3) Below 130% of poverty:	840,731,650:		888,610,000:		+71,850,000:	960,460,000:	
Total, School Breakfast.....	899,177,650:		950,385,000:		+76,845,000:	1,027,230,000:	
(c) CACFP:							
(1) Meal Service....							
(a) Above 185% of poverty:	524,403,000:		608,624,000:		+88,060,000:	696,684,000:	

PROJECT STATEMENT
(On basis of available funds)

	1993		1994		Increase	1995	
	Actual		Estimated		or	Estimated	
Project	Amount	Sys	Amount	Sys	Decrease	Amount	Sys
(b) 130-185%							
of poverty:	37,371,000:		47,240,000:		+3,943,000:	51,183,000:	
(c) Below 130%							
poverty	643,750,804:		790,411,000:		+81,194,000:	871,605,000:	
Subtotal.....	1,205,524,804:		1,446,275,000:		+173,197,000:	1,619,472,000:	
(2) Audit							
expense.....	15,649,297:		21,561,000:		+2,415,000:	23,976,000:	
Child and Adult:					(4):		
Care Food							
Program.....	1,221,174,101:		1,467,836,000:		+175,612,000:	1,643,448,000:	
(d) Summer Food							
Service					(1) (5):		
Program.....	228,006,309:	35:	232,891,000:	40:	+23,673,000:	256,564,000:	37
(e) State Admin:					(6):		
expenses.....	78,475,928:	30:	89,449,000:	15:	+4,592,000:	94,041,000:	15
2. Commodity							
Procurement							
(a) Commodities:	183,950,627:		187,435,000:		+16,308,000:	203,743,000:	
(b) Cash-in-lieu:							
of commodities:	46,647,200:		47,446,000:		+4,128,000:	51,574,000:	
Total, Commodity:					(1) (7):		
procurement. 1/:	230,597,827:		234,881,000:		+20,436,000:	255,317,000:	
3. Coordinated					(8):		
Review.. 1/.....	4,017,146:	62:	3,849,000:	72:	-0-:	3,849,000:	66
4. Nutrition							
Studies and							
Education....							
(a) Nutrition							
Studies and							
Surveys.....	3,835,000:		3,835,000:		-172,000:	3,663,000:	
(b) Nutrition Ed:							
and training:	9,999,875:		10,270,000:		-0-:	10,270,000:	
(c) Food Service:							
Management							
Institute....	1,661,000:		1,853,000:		-147,000:	1,706,000:	
(d) Dietary							
Guidelines..	450,000:		3,604,000:		+16,893,000:	20,497,000:	
Total, Nutrition:							
Studies and					(9):		
Education.. 1/.	15,945,875:		19,562,000:		+16,574,000:	36,136,000:	
TOTAL,							
Obligations....	6,807,338,775:	127:	7,270,749,000:	127:	+482,267,237:	7,753,016,716:	118
Recovery of							
prior year							
Obligations....	-56,450,674:		--		--	--	
Unobligated Bal:							
Available Start:							
of-year.....	-26,767,817:		-75,283,716:		-226,382,000:	-301,665,716:	
Available End-							
of-year.....	+75,283,716:		+301,665,716:		-301,665,237:	--	
Expiring.....	+27,149,000:		--		--	--	
Total,							
Available or							
Estimate.....	6,826,553,000:	127:	7,497,131,000:	127:	-45,780,000:	7,451,351,000:	118

1/ Fiscal Year 1995 amounts include a request of \$32,529,000 in discretionary additions to the mandatory baseline.

EXPLANATION OF PROGRAM

Overview of Program Development. The Child Nutrition Programs, authorized by the National School Lunch Act (NSLA) and the Child Nutrition Act of 1966, subsidize meals served to children in schools and in a variety of other institutions. The Child Nutrition Programs have their origins in commodity distribution programs operated in the 1930's. In 1946, the NSLA established the National School Lunch Program "to safeguard the health and well-being of the Nation's children and to encourage the domestic consumption of nutritious agricultural commodities."

In 1966, Congress expanded the availability of Federal food assistance for children by providing for a pilot breakfast program, which was made a permanent program in 1975. Meal service was extended to pre-school age children in child care in 1968. In 1969, Congress made provisions to assist feeding programs in serving meals for free or at a reduced price to children who met certain income eligibility guidelines. A Summer Food Service Program was initiated in 1968 to serve low income children while school was out of session. The Child Nutrition and WIC Reauthorization Act of 1989 (P.L. 101-147) reauthorized the Summer Food Service Program, State Administrative Expenses, the Commodity Distribution Program and the Nutrition Education and Training Program through 1994.

Eligibility and Benefits. A general description of eligibility for and benefits of the programs follows:

1. Cash Payments to States. The programs are operated under an agreement entered into by State agencies and the Department. Funds are made available by letters of credit to State agencies for use in reimbursing participating schools and other institutions. Sponsors make application to the State agencies and, if approved, are reimbursed on a per-meal basis in accordance with the terms of their agreements and the rates prescribed by law. The reimbursement rates are adjusted annually to reflect changes in the Consumer Price Index for Food Away From Home as provided for in Section 11 of the NSLA.
 - (a) National School Lunch Program (NSLP). Assistance is provided to the States for the service of lunches and snacks to children in participating schools and institutions, regardless of household income. Additional assistance is provided to the States for serving lunches and snacks free or at a reduced price to needy children. States must match a portion of the Federal cash grant. Schools which, in the second previous school year, served at least 60 percent of their lunches at free or reduced prices receive an additional two cents per meal in assistance.
 - (b) School Breakfast Program (SBP). Federal reimbursement is based on the number of breakfasts served to children from low, lower or upper income families. Schools that served at least 40 percent of their lunches at free or reduced prices in the second preceding year and had unusually high preparation costs which exceeded regular breakfast per meal reimbursement, receive higher subsidies in both the free and reduced price categories. FNS also provides expansion grants as authorized by P.L. 101-147, the Child Nutrition and WIC Reauthorization Act of 1989.
 - (c) Child and Adult Care Food Program (CACFP). Nonprofit child care centers and family and group day care homes receive subsidies for meals served to preschool and other children. Profit-making child care centers receiving compensation under Title XX of the Social Security Act may participate in the program if 25 percent of the children enrolled are Title XX participants. Certain adult day care centers are also eligible for participation in this program if they provide meals to persons 60 years or older or to adults who are functionally impaired. They must be nonprofit unless they receive compensation under Title XIX or Title XX of the Social Security Act for at least 25 percent of their enrollees. The Child and Adult Care Food Program provides reimbursement to State agencies at varying rates for breakfasts, lunches, suppers and meal supplements. While meals served to children in centers are means tested, with higher subsidies going to meals served to low income children, all meals are served free in day care homes, with homes receiving the higher free reimbursement rate regardless of the child's family income. Two percent of total CACFP obligations from the second preceding year are provided for audits and administrative reviews of CACFP institutions. As authorized in Public Law 101-147, FNS will, through the end of Fiscal Year 1994, continue to administer grants to homeless shelters to determine the most effective way of providing meals to homeless children under the age of six.

- (d) Summer Food Service Program. Meals served free to children in low-income neighborhoods during the summer months are supported on a per-meal basis by Federal cash subsidies to State agencies. Funds are also provided for related State and local administrative expenses.

The Child Nutrition and WIC Reauthorization Act of 1989 added a new section (q) to Section 13 of the NSLA which requires the Secretary to "establish a system under which the Secretary and States shall monitor the compliance of private nonprofit organizations." In recognition of the vulnerability of this class of summer program sponsors to program abuse, 1/2 of 1 percent of the funds appropriated are authorized to carry out this function.

- (e) State Administrative Expenses. These funds may be used for State employee salaries, benefits, support services and office equipment. The total amount of State Administrative Expenses available for allocation to States is equal to 1.5 percent of Federal cash program payments for the National School Lunch, School Breakfast, Child and Adult Care Food and Special Milk Programs in the second previous fiscal year. Some States are prohibited by law and some States choose not to administer the programs in private schools and institutions. In these States, FNS directly administers the programs through its regional offices.

2. Commodity Procurement. Entitlement commodities and cash-in-lieu thereof required under section 6(e) of the National School Lunch Act (NSLA) are provided from two sources: funds appropriated to the Child Nutrition Programs and funds available to the Agriculture Marketing Service (AMS) under section 32 of the Act of August 24, 1935. Commodities are purchased for distribution to the School Lunch, Child and Adult Care Food and Summer Food Service Programs. The minimum, or "entitlement" commodity support rate for all school lunch and child care center lunches and suppers served is mandated by section 6(e) of the National School Lunch Act and is adjusted annually on July 1 to reflect changes in the Producer Price Index for Food Used in Schools and Institutions.

Section 32. This authority provides for purchase of perishable non-price support commodities when it is necessary to stabilize market conditions. Within the constraints of market conditions, seasonality of crops, and other factors, these purchases are planned so that commodities are delivered to schools on a regular basis throughout the year. The typical commodities purchased include meat, poultry, fish, fruits and vegetables.

Section 6(e) of the National School Lunch Act. Although market considerations play a role, this authority can be used to purchase price support and non-price support commodities based on recipient need and preference. Section 6(e) funds are used to provide schools with some of the perishable foods, such as meat, as well as non-perishable price support commodities (grains, oil, and peanut products) that they need. In addition, section 6(e) funds are used to provide cash-in-lieu of commodities when authorized by law. The areas currently receiving cash-in-lieu of commodities are Kansas, the sites which participated in the study of alternatives to commodity donation and which received commodity assistance in the form of cash-in-lieu of commodity letters of credit, adult care centers and child care centers which may elect to receive all of their commodity entitlement in cash.

Bonus Commodities. In addition to entitlement commodities, when supplies permit, "bonus" commodities are provided to schools and institutions. Outlets can obtain as much of some bonus commodities as they can use without waste; other bonus commodities are offered on a limited basis. Commodities are purchased by AMS and the Commodity Credit Corporation (CCC) and then donated to FNS for distribution. The two sources of bonus commodities are the Price Support Program and the Surplus Removal Program.

Price Support Program. When the Commodity Credit Corporation (CCC) acquires significant inventories of price support commodities, section 416 of the Agricultural Act of 1949 authorizes the CCC to donate commodities from its inventory to schools and other institutions. During Fiscal Year 1992, the Department donated butter, honey, flour and corn meal.

Surplus Removal Program. Under the provisions of section 32, funds are available for emergency surplus removal purchases. The Secretary of Agriculture determines when perishable commodities such as fruits and vegetables should be purchased and donated to schools and institutions under this surplus removal authority.

Coordinated Review Effort

FNS conducts program reviews in cooperation with State agencies in the National School Lunch Program (NSLP) to evaluate the accuracy of local and State meal service data, and provides training and technical support to schools to help improve local program administration and accountability. The Coordinated Review Effort replaces the Federal Review System and the State-conducted Assessment, Information, and Monitoring System (AIMS).

State training and transition activities occurred during the first quarter of Fiscal Year 1993 with actual reviews beginning before January. Fiscal Year 1994 marks the first full year of Coordinated Review with all phases fully implemented.

4. Nutrition Studies and Education

- (a) Nutrition Studies and Surveys. Section 6(a)(3) of the NSLA authorizes the use of Child Nutrition Program funds for nutrition studies and surveys. The purpose of these studies and surveys is to provide descriptive and evaluative information about the programs in order to make informed decisions and improve program operations.
- (b) Nutrition Education and Training (NET). This program, established in 1977 by P.L. 95-166, the National School Lunch Act and Child Nutrition Amendments of 1977, provides funds to State agencies for the development of comprehensive nutrition education and information programs for children participating in or eligible for school lunch and related Child Nutrition Programs. NET provides direct educational benefits to children. The program goals for NET include the instruction of educators and students in the fundamentals of nutrition, training of school food service personnel in nutrition and food service management, and helping children to build good food habits. Nutrition education resources and curricula are identified, developed and disseminated through NET.
- (c) Food Service Management Institute (FSMI). A Food Service Management Institute has been established in Mississippi to provide instruction for educators and school food service personnel in nutrition and food service management.
- (d) Dietary Guidelines. This funding will continue to provide support to schools and child care providers in implementing the Dietary Guidelines for Americans in food service operations. The base request will fund meal pattern analysis and assessment, menu planning technical aids, recipe development and training, and assistance to State and local food service operators. The requested increase will provide Federal and State technical assistance and computer equipment support to school districts for implementing the Dietary Guidelines in school food service operations. FNS will develop national multimedia nutrition education materials for pre-school and school-age children.

State/Federal Responsibilities. The Child Nutrition Programs are operated through a State/Federal partnership under agreements signed by State educational, agricultural, social service or health agencies and FNS. Through this Federal/State partnership, FNS has agreements with 85 State agencies. There are about 20,000 School Food Authorities which oversee the activities of over 92,700 schools, about 59 percent of which offer both lunch and breakfast. Typical Summer Food Service Program sponsors include School Food Authorities and local county or municipal governments. Currently there are over 3,000 sponsors for the Summer Food Service Program and over 12,000 sponsors of the Child and Adult Care Food Program (CACFP). There are currently over 200,000 child care centers and family day care homes participating in the CACFP.

FNS provides cash reimbursements for meals served by type and ensures that appropriate commodities are delivered on a timely basis. Funds are provided to help defray State administrative expenses. FNS also promulgates rules

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implementing the programs as defined by statute, including specifying nutritional requirements for the meals (i.e., meal patterns), meal counting and reporting procedures to ensure confidentiality of free and reduced price meal recipients while assuring accurate counts; requirements for cash and facilities management; and other administrative requirements.

JUSTIFICATION OF INCREASES AND DECREASES

The Fiscal Year 1995 request for the Child Nutrition Programs reflects a decrease of \$45,780,000.

(1) A decrease of \$899,000 for administrative efficiency.

Need for Change. In support of the President's Executive Order to promote the efficient use of resources for administrative purposes, USDA is committed to reducing administrative costs.

Nature of Change. In order to achieve this savings, the Child Nutrition Programs will reduce discretionary expenses by \$899,000 in Fiscal Year 1995. This includes savings of \$163,000 in the Summer Food Service Program, \$539,000 in Commodity Procurement and \$197,000 in Coordinated Review.

(2) A decrease of \$368,679,000 in the appropriation for the School Lunch Program (\$4,503,445,000 appropriated in 1994). On the basis of available funds, there is an increase of \$164,535,237 (\$4,271,896,000 available in 1994).

Need for Change. The total number of school lunches is expected to increase by 34 million in Fiscal Year 1995 due to higher school enrollment and an increase in the number of children applying for free meals. The number of free meals is projected to increase by slightly less than 1% in Fiscal Year 1995. The projected rise in reimbursement rates on July 1 reflecting increases in the Consumer Price Index (CPI) for Food Away from Home contributes to the need for increased funding.

Nature of Change. The requested level of \$4,134,766,000 will be needed in Fiscal Year 1995 for the School Lunch Program to provide full reimbursement for meal service currently projected for Fiscal Year 1995.

School Lunch Program Program Performance Data

	1993 <u>Actual</u>	1994 <u>Estimate</u>	1995 <u>Estimate</u>	<u>Change</u>
Meals served (millions):				
Above 185% of poverty-----	1,873	1,844	1,859	+15
130%-185% of poverty-----	288	291	293	+2
below 130% of poverty-----	<u>1,978</u>	<u>2,049</u>	<u>2,066</u>	<u>+17</u>
	4,139	4,184	4,218	+34
Average participation: (millions)	24.8	25.0	25.3	+.3
Average subsidy per meal (cents):				
Above 185% of poverty-----	16.3	16.6	17.1	+.5
130%-185% of poverty-----	130.0	133.3	138.4	+5.1
Below 130% of poverty-----	170.2	173.5	178.6	+4.6
Commodities-----	14.0	14.0	14.3	+.3
PROGRAM TOTAL - Current Law (millions)	\$4,130	\$4,272	4,436	+164

(3) An increase of \$76,845,000 in the appropriation for the School Breakfast Program (\$950,385,000 available in 1994).

Need for Change. An increase of 51 million meals is projected for Fiscal Year 1995. This increase is due in part to School Breakfast Program expansion grants awarded in previous years.

The projected rise in reimbursement rates on July 1 reflecting increases in the CPI for Food Away from Home contributes to the need for increased funding.

Nature of Change. An appropriation of \$1,027,230,000 will be needed in Fiscal Year 1995 for the School Breakfast Program. This is an increase of about 8 percent over the estimate for Fiscal Year 1994. The number of meals projected for Fiscal Year 1995 is 1,041 million. This represents an increase of 4.2 percent over the 1994 level.

School Breakfast Program
Program Performance Data

	1993 <u>Actual</u>	1994 <u>Estimate</u>	1995 <u>Estimate</u>	<u>Change</u>
Meals served (millions):				
Above 185% of poverty---	112	121	127	+6
130%-185% of poverty----	47	50	53	+3
Below 130% of poverty---	<u>762</u>	<u>819</u>	<u>861</u>	<u>+42</u>
	921	990	1,041	+51
Average participation (millions)-----	5.5	5.9	6.2	+ .3
Average subsidy per meal (cents):				
Paid-----	18.8	19.1	19.6	+ .5
Reduced price:				
Regular-----	64.8	66.5	69.3	+2.8
Severe need-----	82.6	84.8	87.9	+3.1
Free:				
Regular-----	94.9	96.6	99.4	+2.8
Severe need-----	112.6	114.7	117.9	+3.2
PROGRAM TOTAL - Current Law (millions)	\$889.2	\$950.4	\$1,027.2	+76.8

- (4) An increase of \$175,612,000 in the appropriation for the Child and Adult Care Food Program (\$1,467,836,000 available in 1994).

Need for Change. The current request projects an increase of 193 million meals for Fiscal Year 1995 in child care centers, family day care homes and adult day care centers.

The rise in reimbursement rates on July 1 reflecting increases in the CPI for Food Away from Home will contribute to the need for increased funding.

Nature of Change. An appropriation level of \$1,643,448,000 will be needed in Fiscal Year 1995 to provide full reimbursement for meals served in the Child and Adult Care Food Program.

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Child and Adult Care Food Program
Program Performance Data

	1993 <u>Actual</u>	1994 <u>Estimate</u>	1995 <u>Estimate</u>	<u>Change</u>
Meals served (millions):				
Centers				
Above 185% of poverty--	188	217	238	+21
130%-185% of poverty---	49	57	63	+6
below 130% of poverty--	<u>389</u>	<u>465</u>	<u>545</u>	<u>+80</u>
	626	739	846	+107
Family Day Care Homes-----	664	744	830	+86
Average subsidy per meal (cents):*				
Above 185% of poverty--	16.2	16.5	16.9	+.4
130%-185% of poverty---	87.7	90.5	98.0	+7.5
Below 130% of poverty--	117.9	119.7	124.8	+5.1
Commodities-----	14.0	14.0	14.4	+.4
*Family Day Care Homes--	109.9	112.3	123.8	+11.5
PROGRAM TOTAL - Current Law (millions)	\$1,221	\$1,468	\$1,643	+175

*Rates are a blend of all reimbursement levels within an income category.

- (5) A net increase of \$23,673,000 in the appropriation for the Summer Food Service Program (\$232,891,000 appropriated in 1994). The increase consists of:

- (a) A decrease of \$163,000 for administrative efficiency below the Fiscal Year 1995 current services level.
- (b) An increase of \$20,000 for pay costs.
- (c) An increase of \$23,816,000 in grants to States for the Summer Food Service Program.

Need for Change. An increase of 7.6 million meals is projected for Fiscal Year 1995 for a total of 124.9 million meals. The projected rise in the reimbursement rate on January 1 reflecting increases in the CPI for Food Away from Home will contribute to the need for increased funding.

Nature of Change. An appropriation of \$256,564,000 will be needed in the Summer Food Service Program in Fiscal Year 1995 to provide full reimbursement for meals served and continuation of program operations.

Summer Food Service Program
Program Performance Data

	1993 <u>Actual</u>	1994 <u>Estimate</u>	1995 <u>Estimate</u>	<u>Change</u>
Meals served (millions):				
Summer Food Program----	109.2	117.3	124.9	+7.6
Average subsidy per meal (cents):				
Summer rates:				
Lunch-----	204.2	208.3	216.0	+7.7
Breakfast-----	113.8	116.0	120.0	+4.0
Supplements-----	54.0	55.0	57.0	+1.5
PROGRAM TOTAL - Current Law (millions)-----	\$228.0	\$232.9	\$256.6	+23.7

Staff Years:

Reviews	15	20	19	-1
Direct Administration	20	20	18	-2
Total Staff Years:	35	40	37	-3

- (6) An increase of \$8,209,000 in the appropriation for State Administrative Expenses (\$85,832,000 appropriated in 1994). The increase consists of:

- (a) An increase of \$18,000 for pay costs which will provide for the effects of inflation.
- (b) An increase of \$8,191,000 for State administrative expenses.

Need for Change. The increase is due to the rise in meal service in Fiscal Year 1993 which is the base year for grant formulation.

Nature of Change. An appropriation of \$94,041,000 will be needed in Fiscal Year 1995 for State Administrative Expenses. Each State will receive a grant of at least one percent of the funds expended by the State during Fiscal Year 1992 with a minimum grant of \$100,000. The funds available above the basic grant will be allocated to the States to improve program administration.

State Administrative Expenses. State Administrative Expense funds are used for State employee salaries, benefits, support services and office equipment. The total amount of State Administrative Expenses available for allocation to States is equal to 1.5 percent of Federal cash program payments for the National School Lunch, School Breakfast, Child and Adult Care Food and Special Milk Programs in the second previous fiscal year. Some States are prohibited by law and some States choose not to administer the programs in private schools and institutions. In these States, FNS directly administers the programs through its regional offices. In Fiscal Year 1995, approximately \$0.5 million of the estimated \$94 million in State Administrative Expense funds will be applied to FNS costs of directly operating Child Nutrition Programs in seven States. In Fiscal Year 1994, New York will begin operation of the CACFP, relieving FNS of this responsibility. Staff years currently assigned to this work will be reassigned to other work.

- (7) A net increase of \$20,436,000 in the appropriation for Commodity Procurement (\$234,881,000 available in 1994). The increase consists of:

- (a) A decrease of \$539,000 for administrative efficiency below the Fiscal Year 1995 current services estimate.
- (b) An increase of \$20,975,000 for commodity procurement activities.

Need for Change. Overall Federal entitlement commodity support will increase by about \$20 million in Fiscal Year 1995 as required by law.

Nature of Change. An appropriation of \$255,317,000 will be needed to fund all aspects of commodity procurement in Fiscal Year 1995.

Commodities. FNS commodity activity includes funding for food as well as for administrative costs associated with purchasing, distributing and tracking child nutrition commodities. In Fiscal Year 1995, \$719,000 is budgeted for Agricultural Marketing Service administrative costs resulting from commodity purchasing and shipping activities. Administrative costs budgeted for the Agricultural Stabilization and Conservation Service total about \$1.9 million. Computer support costs for the Software Renewal Project, State connectivity, and the National Computer Center (NCC) processing total \$1.3 million. Funding is also included for the operation of PCIMS which was developed to provide more accurate information on commodity purchases, allocation and payments. The current estimate for 1995 reflects a change in the projected commodity reimbursement rate based on a forecast of the Producer Price Index.

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Commodity Cost Data
(\$ millions)

	1993 Actual	1994 Estimate	1995 Estimate	Change
School Lunch:				
CN Appropriation:				
Commodity Purchases-----	195.8	186.0	203.2	+17.2
Administrative Costs				
Computer Support-----	.6	1.3	1.3	--
AMS Admin-----	.1	.5	.7	+2
ASCS Admin-----	.8	1.7	1.9	+2
PCIMS-----	.8	2.8	3.3	+5
Section 32 Commodities-----	400.0	400.0	400.0	--
School Lunch Total-----	598.1	592.3	610.4	+18.1
Child and Adult Care				
Commodities/Cash-----	31.3	41.3	43.6	+2.3
Summer Food Service				
Commodities	1.2	1.3	1.3	--
TOTAL COMMODITY COSTS				
(Current Law)	\$630.6	\$634.9	\$655.3	+20.4

- (8) No net change in the appropriation for the Coordinated Review Effort (\$3,849,000 available in 1994). The request consists of:

- (a) A decrease of \$197,000 for administrative efficiency below the Fiscal Year 1995 current services estimate.
- (b) An increase of \$161,000 in the funding level for school operations.
- (c) An increase of \$36,000 for pay costs.

Need for Change. The Coordinated Review Effort (CRE) was authorized by P.L. 101-147, the WIC and Child Nutrition Reauthorization Act of 1989. Federal personnel work with State and local personnel to conduct management evaluations and local program reviews to ensure that meals are being counted and claimed accurately.

Nature of Change. An appropriation of \$3,849,000 will be needed in Fiscal Year 1995 to fund the Coordinated Review Program.

- (9) An increase of \$18,124,000 in the appropriation for Nutrition Education, Nutrition Studies and Surveys, the Food Service Management Institute and the Dietary Guidelines (\$18,012,000 available in 1994).

Need for change. This amount represents a decrease of \$172,000 in studies and surveys, a decrease of \$147,000 in the Food Service Management Institute, an increase of \$8,443,000 for implementing the Dietary Guidelines, and an increase of \$10,000,000 for Nutrition Education Assistance. This increase expands the Agency's and States' capability to make changes to conform to the Dietary Guidelines in meals and provide basic levels of nutrition education.

Nature of change. An appropriation of \$36,136,000 will be needed to fund these activities in Fiscal Year 1995.

Nutrition Studies and Surveys is authorized in Section 6(a)(3) of the National School Lunch Act for necessary surveys and studies of the requirements for food service programs. The 1995 request of \$3,663,000 will be used to fund studies of program operations and to assist in implementation of the Dietary Guidelines.

Nutrition Education and Training. The requested funding level of \$10,270,000 for the Nutrition Education and Training Program is within the level authorized in Section 19(1)(2) of the Child Nutrition Act of 1966.

Food Service Management Institute. The request includes \$1,706,000 for maintenance of operations at the Food Service Management Institute, which was authorized by Public Law 101-147.

Dietary Guidelines. This funding will continue to provide support to schools and child care providers in implementing the Dietary Guidelines for Americans in food service operations. The request of \$20,497,000 will support all Child Nutrition Programs and provide meal pattern analysis and assessment, menu planning technical aids, recipe development, training and assistance to State and local food service operators and provide incentives for school districts to meet the Dietary Guidelines. Increased technical assistance is necessary for school districts to implement the Dietary Guidelines in food service by 1998. The funding level will also allow the Secretary to develop national nutrition education programs for pre-school and school-age children. FNS will use the Department's extensive electronic resources to provide print and video nutrition education materials for audiences served by the Child Nutrition Programs.

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CHILD NUTRITION PROGRAMS

STATUS OF PROGRAM

Child Nutrition Programs

The National School Lunch and Child Nutrition Acts as amended, authorize a number of food service programs for children in schools and other institutional settings. These programs include the National School Lunch, School Breakfast, Child and Adult Care Food and Summer Food Service Programs. In addition, the Child and Adult Care Food Program provides for food service for certain impaired adults. Each of these programs uses the same income poverty thresholds, their administrative structures are similar including emphasis on nutrition and nutrition education, and some entities can operate several of the programs at the same time. The Acts also authorize funding to help States pay the administrative expenses associated with these programs, for a Nutrition Education and Training Program and for the costs of certain nutrition studies and surveys. Funds are also provided for the continued support of a Food Service Management Institute, the Processed Commodity Inventory Management System (PCIMS) and the computer support activities which aid in transition from contractor to FNS in-house maintenance of Special Nutrition Programs software renewal systems.

The Food and Nutrition Service (FNS) is responsible for the nationwide administration of the Child Nutrition Programs. Cooperating State agencies administer the programs in public schools and institutions. A number of State agencies administer the programs for nonprofit private schools and institutions as well. However, some States are prohibited by law and some States choose not to administer the programs in private schools and institutions. In these States, FNS directly administers the programs through its regional offices. Nonetheless, under the Omnibus Reconciliation Act of 1981, P.L. 97-35, no State which administered the Child Nutrition Programs since October, 1980 can request that FNS administer them.

National School Lunch Program

States are reimbursed on the basis of the number of meals served to children in participating schools at reimbursement rates which vary according to family need. Children from families which meet certain income guidelines can qualify for free or reduced price lunches. Income eligibility for free meals is set at or below 130 percent of the Federal income poverty guidelines and eligibility for reduced price meals is set at between 130 and 185 percent. For the period July 1, 1993 to June 30, 1994, a child from a family of four with an annual income of \$18,655 or less will be eligible for free meals, and for reduced price meals if the family income is no more than \$26,548.

On an average school day in Fiscal Year 1993, an estimated 24.8 million children participated in the National School Lunch Program, compared to an estimated 24.6 million children in Fiscal Year 1992. The total number of participating schools and residential child care institutions increased from about 92,660 in Fiscal Year 1992 to about 92,947 during Fiscal Year 1993.

Per-meal reimbursement rates for meals served are revised on July 1 of each year. For the period July 1, 1993 to June 30, 1994, the cash reimbursement rates are as follows: section 4 rate paid for all eligible meals is \$0.1650; section 11 free rate is \$1.5600; section 11 reduced price rate is \$1.1600. The cash reimbursement per free or reduced price meal is the sum of section 4 and section 11 reimbursement rates. In addition, the commodity assistance rate is \$0.14 for all eligible meals. School food authorities which served 60 percent or more free and reduced price lunches during the second preceding year receive increased assistance at the rate of \$.02 per meal served. The following table compares the lunches served in the three income categories for Fiscal Years 1992 and 1993.

	FY 1992	FY 1993	Percent Change
Number of lunches served (millions):			
Upper income	1,926	1,873	-2.8
Lower income	285	288	+1.0
Low income	<u>1,891</u>	<u>1,978</u>	<u>+4.6</u>
Total Lunches	4,102	4,139	+ .9

School Breakfast Program

This program, initially authorized as a two-year pilot program under the Child Nutrition Act of 1966, was made permanent in October 1975. For each breakfast served, schools are reimbursed at established free, reduced price and paid meal rates. Schools which serve 40 percent or more of their lunches during the second preceding school year at the reduced price and/or free rates are eligible for "severe need" assistance calculated at established rates.

The income eligibility guidelines for the School Breakfast Program are the same as those for the National School Lunch Program. The School Breakfast Program is available to the same schools and institutions as the National School Lunch Program.

In Fiscal Year 1993, school breakfasts were available to approximately 26.5 million children daily in schools and institutions. Between October 1992 and October 1993, the number of schools and institutions participating in the breakfast program increased by about 8.7 percent. The average number of children eating breakfasts daily increased from an estimated 4.9 million in Fiscal Year 1992 to an estimated 5.5 million in Fiscal Year 1993. In Fiscal Year 1993, 921 million breakfasts were served as compared to 853 million in Fiscal Year 1992.

The rates in effect from July 1, 1993 to June 30, 1994 are as follows: paid rate - \$0.1900; regular reduced price rate - \$0.6600; regular free rate - \$0.9600; severe need reduced price rate - \$0.8425; severe need free rate - \$1.1425.

The Child Nutrition and WIC Reauthorization Act of 1989 authorized \$5 million in Fiscal Years 1991-1994 for startup grants for new school breakfast programs serving low-income children. Through Fiscal year 1993, a total of \$18 million in startup grants have been awarded in 38 States. Grants were awarded on the basis of need, number of children to be added to the Program, and feasibility and cost-effectiveness of States' proposals. Grant money was spent by school districts for capital expenditures, equipment, outreach materials and training of food service staffs.

Summer Food Service Program

The Summer Food Service Program, authorized under section 13 of the National School Lunch Act, provides funds for food service for needy children during summer vacation. Service institutions eligible to participate in this program are limited to those serving children from areas in which poor economic conditions exist. Furthermore, these institutions must be public or private non-profit schools, other public entities, sites serving homeless children, colleges and universities that operate the National Youth Sports Program, private non-profit organizations that meet certain criteria and residential camps. Meals are served free to all participants ages 1-18 and are limited to lunch and either breakfast or a supplement, except in summer camps and migrant programs which may serve breakfast, lunch, supper and a supplement to each participant daily.

In addition to cash support, commodities are distributed to summer program sponsors that are schools and/or prepare their own meals or obtain them from schools. Funds are also made available to conduct health inspections and to defray State and local administrative costs.

In the summer of 1993, FNS administered the program in six States. The balance of the program was operated by State agencies. During July, the peak month of program operations, approximately 2.1 million children participated in the program. Over the course of the summer, an estimated 109 million meals were served at an estimated cost of \$228 million.

Child and Adult Care Food Program

Authorized under section 17 of the National School Lunch Act, the Child and Adult Care Food Program provides cash and commodities or cash-in-lieu of commodities for food service for children in non-residential child care centers and family day care homes and for chronically impaired adults and persons 60 years of age or older who are enrolled in adult day care centers. The centers must be either nonprofit facilities, or for-profit centers with at least 25 percent of their enrollment receiving Title XX funds. As part of a demonstration project, homeless children under age 6 are also eligible for the program if they reside in approved emergency shelters. Adult day care centers may also participate if 25 percent of their enrollment receives Title XIX funds. Providers must be licensed or approved according to Federal, State or local standards. In addition, funds are made available to the States for audit expenses associated with the administration of the Child and Adult Care Food Program. Effective, April 1, 1993, the New York State

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Department of Health assumed responsibility from FNS for administration of the Child and Adult Care Food Program in New York. FNS now directly administers the Child and Adult Care Program in one State--Virginia.

The Child and Adult Care Food Program operates two separate components, depending upon whether food is provided to recipients in child care centers or child care homes. Overall in Fiscal Year 1993, average daily attendance was approximately 1.9 million participants, as compared to 1.8 million in Fiscal Year 1992. The number of meals served increased by 9.3 percent from 1.18 billion meals in Fiscal Year 1992 to about 1.29 billion meals in Fiscal Year 1993. About 1.1 million participants were served in centers and 800,000 in homes. Centers average about 70 children and receive free, reduced price and paid meal reimbursements under the program via taking income applications and counting meals served by type and by recipient eligibility type. Homes typically have 5 or 6 children and receive a single reimbursement rate for each meal.

Commodity Procurement

The commodity subsidy for the National School Lunch, and Child and Adult Care Food Programs is authorized by section 6(e) of the National School Lunch Act and is based on a "rate per meal" concept; while section 13(h) authorizes commodity assistance for the Summer Food Service Program. For Fiscal Year 1993, schools, day care centers, and residential institutions were authorized to receive an average of 14.0 cents worth of commodities for each lunch or supper. USDA also provides commodities which are acquired through the price support and surplus removal programs. Therefore, schools and institutions receive both the commodities under the rate per meal subsidy, called "entitlement" commodities, and the commodities which USDA acquires through agricultural programs called "bonus commodities" and donates them to schools.

In Fiscal Year 1993, food and cash, in lieu of commodities valued at \$710.7 million, was provided for the National School Lunch, Child and Adult Care Food and Summer Food Service Programs. This amount includes \$90.2 million of food given to States from Commodity Credit Corporation (CCC) inventories and section 32 surplus removal operations. An additional \$44.3 million in cash-in-lieu of commodities was distributed for child care food programs, which may opt for commodities or cash, to the State of Kansas, the Republic of Palau, and to sites which participated in the study of alternatives to commodity donation and received their commodity assistance in the form of cash-in-lieu of commodities or Commodity Letters of Credit. For the school programs, excluding Kansas, the Republic of Palau, and the school districts which participated in the study, 100 percent of the authorized commodity subsidy in school year 1993 was provided through food donations.

In Fiscal Year 1993, the value of the cash/commodity entitlement was computed to be \$618.1 million for the National School Lunch, Summer Food and Child and Adult Care Food Programs. As with the cash subsidy, this amount was the product of the estimated number of total meals times the commodity rate for the National School Lunch, Child and Adult Care Food Programs, and the Summer Food Service Program. Public Law 101-147 included a new provision for annual reconciliation of commodity assistance or cash-in-lieu of commodities provided to each State. The commodity entitlement will now be based on the meal data from the preceding school year.

For Fiscal Year 1993, commodity assistance to Child Nutrition Programs (including commodities, cash-in-lieu of commodities and administrative costs) totaling \$620.5 million was funded by using \$389.9 million from section 32 funds and \$230.6 million from Child Nutrition Programs appropriated funds. Section 6(e) funds are used to provide cash-in-lieu of commodities when authorized by law. The areas currently receiving cash-in-lieu of commodities are the State of Kansas, the sites which participated in the study of alternatives to commodity donation and which received commodity assistance in the form of cash-in-lieu or Commodity Letters of Credit, nonresidential child care institutions electing to receive their commodity entitlements in cash, and the Republic of Palau. Funding is also included for the Processed Commodity Inventory Management System which integrates the commodity purchasing, tracking, shipping and payments for the commodity activities of FNS, AMS and ASCS. In Fiscal Year 1993, this amounted to a total of \$664 million for commodities used in FNS programs. This computerized system provides greater efficiency, increased accuracy, and more timely and improved reporting capabilities for all users.

Commodity Donations

In addition to commodities purchased to fulfill the Child Nutrition Programs' entitlement, commodities that are acquired by USDA through its agricultural programs may be donated to schools and other institutions when available in inventory in

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sufficient quantities. There are two types of agricultural programs through which commodities are acquired: the price support program and the surplus removal program.

Price Support. During Fiscal Year 1993, the Department donated the following products under the Price Support Program: butter, butter oil, and cornmeal. Section 416 bonus donations to the Child Nutrition Programs were estimated at \$50.8 million in Fiscal Year 1993.

Surplus Removal Program. In Fiscal Year 1993, about \$39.4 million in section 32 bonus commodities were delivered to schools and other eligible child nutrition outlets under the Surplus Removal Program authority. The following table shows the type and value of commodities purchased or donated and the amount of cash-in-lieu of commodities allocated in Fiscal Year 1993.

Value of Commodities in the Child Nutrition Programs

Fiscal Year 1993		Value (\$ in millions)
Financed with funds appropriated to FNS:		
	Meats, poultry, fruit and vegetables.....	57.7
	Grains, oils, peanut products, cheese and flour.....	126.2
Subtotal:	Entitlement commodities.....	183.9
	Kansas and the Republic of Palau.....	7.3
	Child and Adult Day Care Food Program.....	29.2
	Study: Alternatives to Commodity Donations..	7.8
Subtotal:	Cash in lieu of entitlement commodities.....	44.3
	AMS & CCC reimbursement.....	.9
	Processed Commodity Inventory Management System.....	.8
	Update Commodity System Computer Software...	.7
Subtotal:	Cash for Administrative Expenses.....	2.4
TOTAL:	All FNS funds.....	230.6
Value (\$ in millions)		
Financed with funds appropriated to CCC or AMS and "donated" to FNS:		
	Meat, poultry, fish, fruits and vegetables (AMS).....	389.9
	CCC commodities.....	0.0
Subtotal:	Entitlement Commodities.....	389.9
	Butter and cornmeal.....	50.8
	Fruits and vegetables (AMS).....	39.4
Subtotal:	Bonus Commodities.....	90.2
TOTAL:	Entitlement commodities and cash-in-lieu.....	618.1
TOTAL:	Bonus commodities.....	90.2
TOTAL:	Administrative expenses.....	2.4
GRAND TOTAL:		710.7

State Administrative Expenses

FNS makes funds available to the States for program administration and for supervision and technical assistance in local school districts and child care institutions. The Fiscal Year 1993 appropriation was \$77.1 million for State Administrative Expenses. An additional \$5.5 million was made available from recoveries and carryover for a total funding level of \$82.6 million.

Of this amount \$66.6 million was allocated to States under the basic legislative formulas for program administration, an additional \$10.4 million was made available to States to supplement the basic formulas, and \$1.1 million was redistributed to States for justified administrative needs through the reallocation process. Of the amounts allocated to the States for their program administration, \$46.5 million was

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for administration of the school food programs, \$26.5 million was for the administration of the Child and Adult Care Food Program, and \$4.0 million was for the administration of the Food Distribution Program.

Funds for State Administrative Expenses are available to the States for obligation for two years--the year of appropriation and the following year. Thus, States can carry over these funds from the first year into the second year. Preliminary reports indicate that the amount of funds carried over at the State level from Fiscal Year 1993 into Fiscal Year 1994 was about \$15.0 million, an amount equal to 19.4 percent of the Fiscal Year 1993 appropriation for State Administrative Expenses. The State agency may carry over up to 20 percent of the initial allocation amount each fiscal year. Carryover exceeding the 20% limit is recovered. These recovered funds are to be used to provide food service in homeless demonstration projects authorized through Fiscal Year 1994. In accordance with section 7(a)(5)(B)(i) of the Child Nutrition Act of 1966, as amended by P.L. 102-512, at least \$1 million but not more than \$4 million is to be allocated for this purpose in Fiscal Year 1994. For Fiscal Year 1993, \$1 million in SAE funds was allocated for homeless demonstration projects. Approximately \$500,000 of this amount was used. Any funds remaining after the allocation to the homeless demonstration projects are to be allocated to State agencies with a demonstrated need for additional administrative funds.

Child Nutrition Program Research

Agency research priorities for Fiscal Year 1993 included a study to determine the actual costs to produce a school lunch and breakfast, and a study to evaluate the effects a multi-use school lunch application on lunch participation rates. The Agency also continued a dietary assessment of Child Nutrition Programs and studies of food service management companies and the Adult Day Care component of the Child and Adult Care Food Program. In addition, the agency continued a number of congressionally mandated demonstrations, studies, and reports including demonstrations to increase low income participation in the Child and Adult Care Food Program and to serve children in homeless shelters; and studies of alternative counting procedures to reduce paperwork in the National School Lunch Program.

Studies conducted during Fiscal Year 1993 include:

- o School Nutrition Dietary Assessment (SNDA). This study was designed to describe the nutrients and food contained in meals served to students by a nationally representative sample of 545 schools. This study also described the dietary intake of a representative sample of 3,350 students on a typical school day. The foods and nutrients that were offered to students by schools, and the foods and nutrients that were consumed by students over the course of the day, were compared to RDA requirements. Nutrients and foods were also compared to nutrition goals described in the Dietary Guidelines for Americans. The SNDA study found that school meals met RDA standards for nutrients, but did not meet the Dietary Guidelines for total fat.
- o Child Nutrition Program Operations Study--Third Year Report. This three-year panel study was designed to provide descriptive data on Child Nutrition Program characteristics from a nationally representative sample of 1,740 School Food Authorities (SFAs). The third year of the study provides a snapshot of school-based Child Nutrition Programs during School Year 1990-91. This study describes participation in the National School Lunch Program and the School Breakfast Program; meal prices; operations of the Food Donation Program; training and technical assistance; commercial food service vendors; and after-school care. The following findings were reported:
 - o student participation in the NSLP remained relatively constant between School Year 1987-88 and School Year 1989-90.
 - o the School Breakfast Program is available to an increasing number of students.
 - o School Food Authorities reported that reductions in the level of bonus commodity donations had affected their food service operations. Commercial food purchases were increased.
- o Child Nutrition Homeless Demonstration--Year Two. This homeless shelter demonstration was designed to determine the feasibility of providing year-round food assistance to preschool children (under age 6) in homeless shelters. Unlike older homeless children, preschoolers do not have access

to school meals. The Year 2 study found that all participating shelters were able to operate the Child Nutrition Program, and that meal quality increased as a result of the demonstration.

- o School Lunch and Breakfast Cost Study. The primary objective of this study is to determine the full cost of producing reimbursable meals in the National School Lunch Program and School Breakfast Program, including indirect and local administrative costs. This study will estimate these costs using the Meal Cost Methodology Study direct measurement approach in a nationally-representative sample of approximately 100 School Food Authorities (SFAs).
- o 1990 Farm Bill School Lunch Studies. The 1990 Farm Bill (P.L. 101-624) requires the Secretary to examine several issues affecting the National School Lunch Program (NSLP). This study examines the impact of changes in bonus commodity donation levels on the NSLP. The first objective is to determine the quantity of bonus commodities lost, by State, since the 1987-88 school year. The study will also examine the change in determining the price that school food authorities charge.
- o Early Childhood and Child Care Study. This study will examine the nutritional aspects of the child component of the Child and Adult Care Food Program (CACFP). A three-stage cluster sample will be used to develop nationally generalizable estimates of (a) the nutrient content of CACFP meals offered by Head Start child care centers, non-Head Start child care centers, and family day care homes; (b) the extent to which CACFP meals offered by providers meet the Recommended Daily Allowance (RDA) and the dietary intake of the children who participate.

Coordinated Review Effort

FNS conducts National School Lunch Program (NSLP) reviews in cooperation with State agencies to improve school management of the program and to evaluate the accuracy of local meal service data, and provides training and technical support to schools to help improve local program accountability. During School Year 1992, the transition year between the Assessment Improvement & Monitoring System (AIMS) and the Coordinated Review Effort approximately, 7,800 schools in 4,900 school food authorities were reviewed. The result of these reviews was a total of \$687,590 in overclaims and \$20,400 in underclaims nationwide. Reviews under AIMS are not as specific as CRE reviews. As a result, errors by type and overclaims collected are not available on a nationwide basis. Data for School Year 1993, the first full year for the Coordinated Review Effort, will be available in March 1994. FNS fully participates in the conduct of these reviews along with State agencies and anticipates a substantial increase in funds recovered by State agencies based on the improved system. FNS also believes Coordinated Review encourages schools to do a better job and so, in effect, deters a substantial amount of error.

Nutrition Education and Training Program

The Nutrition Education and Training (NET) Program is authorized by section 19 of the Child Nutrition Act. The program provides funds for training school food service personnel in food service management, instructing teachers in nutrition education and teaching children about the relationship of nutrition to health in order to assist them in making wise food choices.

In Fiscal Year 1993, \$10 million was allocated among the States for the NET Program. Final Fiscal Year 1992 State agency reports show that approximately 95 thousand school food service personnel, 145 thousand teachers, and 6.7 million children participated in NET funded projects. During 1994, data is being collected from the States on their key accomplishments and outcomes resulting from the operation of the NET program.

National Commodity Processing Program (NCP)

Using broad CCC authorities and specific Congressional authorities of Public Law 98-8, the Emergency Food Assistance Act, Public Law 99-198, the Food Security Act of 1986, and Public Law 100-237, the Commodity Distribution Reform Act and WIC Amendments of 1987, and the FACT Act of 1990, the Department distributes surplus agricultural commodities from the Commodity Credit Corporation to various outlets using processing agreements with private companies. The NCP Program is authorized through September 30, 1995. Under NCP, the Food and Nutrition Service enters directly into agreements with private food processors to convert specifically designated surplus commodities into a variety of finished end products. Processors holding agreements with FNS sell these products at reduced prices to

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recipient agencies eligible to receive surplus donated commodities. The price reductions reflect the value of donated ingredients contained in the end product.

To ensure program integrity, there is a management information system centralized at the Kansas City Computer Center. This system is an integrated data base capable of storing and editing data and generating management reports for the NCP Program. In this system, data on the more than 32,300 registered recipient agencies, processors, end products, sales and inventory balances are maintained. This computerized management information system has been recognized by private industry and State governments as a model of good management.

In addition to claims determined through evaluation of data contained in the management information system, the Office of Inspector General (OIG) has conducted audits of several companies participating in the NCP Program. Based on the results of these audits, additional claims have been issued. As a result of all these monitoring activities, FNS has recovered in excess of \$7.7 million since the program began in Fiscal Year 1982.

The Processed Commodity Inventory Management System (PCIMS).

The Processed Commodity Inventory Management System (PCIMS) is a tri-agency computer system that supports the Food Distribution Programs of the Department. The Food and Nutrition Service (FNS), the Agricultural Marketing Service (AMS) and the Agricultural Stabilization and Conservation Service (ASCS) use the system to carry out their functions relative to commodity program administration. Fiscal Year 1993 was the first full year of operation.

Currently, PCIMS functions include procurement and delivery of commodities; order processing; entitlement and payment tracking; as well as fund accounting and control for 11 different commodity programs. Accomplishments for Fiscal Year 1993 include:

- o Developed a plan for implementation of electronic data exchange. A pilot project is planned for Fiscal Year 1994;
- o Determined user requirements for on-line funds control which will prevent over obligation and expenditure of commodity funds;
- o Implemented commodity procurement reconciliation procedures and concluded reconciliation of all outstanding prior year balances among the three Agencies.

Suspension and Debarment

FNS has developed procedures and systems to evaluate and process cases subject to the Department's Nonprocurement Suspension and Debarment Authority. Liaison relationships have been established with the Department of Justice and the Defense Logistics Agency. Due to an increase in nonprocurement suspension and debarment case-referrals in Fiscal Year 1993, FNS activity with respect to nonprocurement suspension and debarment actions has increased greatly. FNS has received information concerning criminal milk bid-rigging activity on approximately 50 cases of companies and individuals that may result in a suspension or debarment action. To date, FNS has taken administrative action in five cases in accordance with its authority under the governmentwide Common Rule on Nonprocurement Debarment and Suspension. Two dairies were notified that debarment proceedings would not be initiated due to the protection to FNS programs granted under the Administrative Agreement the companies entered with the Defense Logistics Agency. FNS intends to continue aggressive action on all cases involving firms or individuals found guilty of milk bid-rigging.

SPECIAL MILK AND CHILD NUTRITION PROGRAMS
FINANCING FOR FISCAL YEAR 1993

State or Territory	Special Program	School Lunch	School Breakfast	State Expenses	Commodities and Services	Child Care And	Summer Service	NET	Total Contribution
Alabama	\$32	\$0	\$1	\$1,617,744	\$19,280	\$21	\$4,519	\$15	\$150
Alaska	0	0	0	0	0	0	0	0	0
Arizona	0	0	0	0	0	0	0	0	0
Arkansas	0	0	0	0	0	0	0	0	0
California	0	0	0	0	0	0	0	0	0
Colorado	0	0	0	0	0	0	0	0	0
Connecticut	0	0	0	0	0	0	0	0	0
Delaware	0	0	0	0	0	0	0	0	0
District of Columbia	0	0	0	0	0	0	0	0	0
Florida	0	0	0	0	0	0	0	0	0
Georgia	0	0	0	0	0	0	0	0	0
Hawaii	0	0	0	0	0	0	0	0	0
Idaho	0	0	0	0	0	0	0	0	0
Illinois	0	0	0	0	0	0	0	0	0
Indiana	0	0	0	0	0	0	0	0	0
Iowa	0	0	0	0	0	0	0	0	0
Kentucky	0	0	0	0	0	0	0	0	0
Louisiana	0	0	0	0	0	0	0	0	0
Maine	0	0	0	0	0	0	0	0	0
Maryland	0	0	0	0	0	0	0	0	0
Massachusetts	0	0	0	0	0	0	0	0	0
Michigan	0	0	0	0	0	0	0	0	0
Minnesota	0	0	0	0	0	0	0	0	0
Mississippi	0	0	0	0	0	0	0	0	0
Missouri	0	0	0	0	0	0	0	0	0
Montana	0	0	0	0	0	0	0	0	0
Nebraska	0	0	0	0	0	0	0	0	0
Nevada	0	0	0	0	0	0	0	0	0
New Hampshire	0	0	0	0	0	0	0	0	0
New Jersey	0	0	0	0	0	0	0	0	0
New Mexico	0	0	0	0	0	0	0	0	0
New York	0	0	0	0	0	0	0	0	0
North Carolina	0	0	0	0	0	0	0	0	0
North Dakota	0	0	0	0	0	0	0	0	0
Ohio	0	0	0	0	0	0	0	0	0
Oklahoma	0	0	0	0	0	0	0	0	0
Oregon	0	0	0	0	0	0	0	0	0
Rhode Island	0	0	0	0	0	0	0	0	0
South Carolina	0	0	0	0	0	0	0	0	0
South Dakota	0	0	0	0	0	0	0	0	0
Tennessee	0	0	0	0	0	0	0	0	0
Texas	0	0	0	0	0	0	0	0	0
Vermont	0	0	0	0	0	0	0	0	0
Virginia	0	0	0	0	0	0	0	0	0
West Virginia	0	0	0	0	0	0	0	0	0
Wisconsin	0	0	0	0	0	0	0	0	0
Wyoming	0	0	0	0	0	0	0	0	0
American Samoa	0	0	0	0	0	0	0	0	0
Guam	0	0	0	0	0	0	0	0	0
Marshall Islands	0	0	0	0	0	0	0	0	0
Puerto Rico	0	0	0	0	0	0	0	0	0
Virgin Islands	0	0	0	0	0	0	0	0	0
Washington	0	0	0	0	0	0	0	0	0
Yukon	0	0	0	0	0	0	0	0	0
Unallocated	0	0	0	0	0	0	0	0	0
Virgin Islands	0	0	0	0	0	0	0	0	0
Indian Trust Lands	0	0	0	0	0	0	0	0	0
Freely Associated States	0	0	0	0	0	0	0	0	0
AMS/ACT/PLNS/Ship Non-Ex	0	0	0	0	0	0	0	0	0
Undistributed	0	0	0	0	0	0	0	0	0
TOTAL	\$19,108,710	\$4,129,943	\$899,177,650	\$78,475,928	\$710,632,000	\$1,221,174,101	\$228,006,309	\$9,999,875	\$7,296,518,512

NOTE: Data is based on obligations as reported September 30, 1993. Commodities are based on preliminary food orders for fiscal year 1993. Totals may not add due to rounding.

31g-9

CHILD NUTRITION PROGRAMS
Quantity and Value of Commodities

School or Fiscal Year 1993

Page 1 of 2

ENTITLEMENT COMMODITIES	Thousands of Pounds	Thousands of Dollars
SECTION 6/32 TYPE:		
APPLE SLICES, CANNED	11,830	\$4,808
APPLES, FRESH	5,510	1,383
APPLESAUCE, CANNED	22,430	6,397
BEANS, DRY	320	123
BEANS, DRY CANNED	10,369	2,524
BEANS, GREEN, CANNED	27,760	7,857
BEANS, GREEN, FROZEN	3,561	1,209
BEANS, REFRIED, CANNED	4,710	1,469
BEANS, VEGETARIAN	7,061	1,424
BEEF PATTIES, FRZ	10,597	14,335
BEEF PATTIES, FRZ W/VPP	22,514	25,067
BEEF PATTIES, EXTRA LEAN	6,771	10,736
BEEF, FROZEN GROUND	92,698	116,522
BEEF, CANNED W/J	504	753
BEEF, FRZ GRD COARSE-PROCESS	12,390	16,035
BLUEBERRIES, FRZ	4,151	3,460
BLACKBERRY FRZ	1,261	964
CHERRIES, FROZEN	7,082	2,911
CHICKENS, CHILLED BULK	10,188	5,594
CHICKENS, CHILL LEG	9,108	4,807
CHICKENS, FROZEN, CUT-UP	31,737	19,869
CHICKENS, FRZ BREADED	11,424	12,544
CHICKENS, NUGGETS FRZ SOC	2,652	4,183
CHICKENS, DICED FRZ	5,271	12,074
CHICKENS, PATTIES SOC	78	121
CORN, CANNED	28,774	9,932
CORN, FROZEN	3,913	1,428
EGGS, WHOLE FROZEN	13,092	6,066
MIXED FRUIT	8,508	4,260
PEACHES, CLING CANNED	22,126	10,537
PEACHES, FREESTONE CND	2,878	1,466
PEACHES, FREESTONE FRZ SLICED	6,374	4,059
PEARS, DICED	11,480	4,517
PEARS, HALVES	14,085	5,556
PEARS, SLICED	7,035	2,755
PEARS, BOSC FRESH	81	20
PEARS, D'ANJOU FRESH	3,521	944
PEAS, GREEN CANNED	10,033	2,577
PEAS, GREEN FROZEN	7,141	2,524
PINEAPPLE, CANNED	857	453
PLUMS, CANNED PITTED	2,263	850
PORK, CANNED W/NJ	540	680
PORK, FRZ GROUND	19,744	20,217
PORK, FRZ GRD COARSE-PROCESS	3,247	3,170
POTATO ROUNDS, FROZEN	21,468	6,453
POTATOES, OVEN FRY	21,299	6,121
RAISINS	4,818	2,470
SALMON, PINK CANNED	2	3
SALSA	2,320	824
SWEET POTATOES, SYRUP	6,231	2,541
TOMATO PASTE, CANNED	40	15
TOMATOES, CANNED	37	12
TUNA	5,406	5,820
TURKEY ROASTS, FROZEN	24,874	34,166
TURKEY, FROZEN GROUND	18,817	11,012
TURKEY, FROZEN WHOLE	12,406	7,612
TURKEY, CHILLED, BULK	13,752	8,212
TURKEY, FRZ GROUND BURGERS	3,348	3,166
Total Section 6/32 Type	622,466	\$447,608

continued on the next page

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CHILD NUTRITION PROGRAMS
Quantity and Value of Commodities

School or Fiscal Year 1993

Page 2 of 2

ENTITLEMENT COMMODITIES	Thousands of Pounds	Thousands of Dollars
SECTION 416-TYPE:		
CHEESE, CHEDDAR	7,517	\$5,553
CHEESE, MOZZARELLA	17,649	23,095
CHEESE, PROCESS	35,926	47,654
FLOUR	114,493	14,483
FLOUR MIX SOC	168	52
GRITS, CORN	264	38
MACARONI	2,492	611
MFD, MILK	6,832	7,009
OATS, ROLLED	1,782	349
OIL, SALAD DRESSING SOC	133	41
OIL, VEGETABLE	31,505	10,011
PEANUT BUTTER	6,976	5,430
PEANUT GRANULES	148	157
PEANUTS, ROASTED	876	850
RICE, BROWN	42	7
RICE, MILLED	15,694	2,936
ROTIMI	1,845	521
SHORTENING, LIQUID VEG	5,409	1,901
SHORTENING, VEGETABLE	11,010	4,560
SPAGHETTI, ENRICHED	3,784	956
Total Section 416-Type	264,544	\$126,214
Anticipated Adjustment		0
Total Commodity Entitlement	887,010	\$573,822
BONUS COMMODITIES		
SECTION 32-TYPE:		
ALMOND BUTTER	483	\$371
ASPARAGUS, CANNED	186	245
ASPARAGUS, FROZEN	8,259	1,868
BEANS, CANNED PINTO	2,596	685
BEANS, DRY	777	245
BEANS, REFRIED	5,621	1,201
BEANS, VEGETARIAN	1,370	1,060
BLACKBERRY PUREE	9,185	3,952
CHERRIES, FROZEN	1,005	363
CHICKENS, DRUMS	1,549	488
CHICKENS, LEG STRS	358	133
CHICKENS, THIGHS	1,853	1,452
DATE PIECES	771	127
GRAPEFRUIT	8,389	2,837
GRAPE JUICE	10,154	5,176
ORANGE JUICE FRZ CONC	600	106
ORANGES	4,630	3,077
PEACHES FRZ	4,006	1,689
PEARS, HALVES	4,953	2,044
PEARS, SLICED	1,438	235
POTATOES, BAKING	7,415	3,858
POTATOES, DEHYDRATED	742	337
POTATOES, GRANULES	299	274
RASPBERRY PUREE, FROZEN	2,250	53
SALMON, PINK CANNED	7,079	2,145
TOMATOES, CRUSHED	4,744	1,763
TOMATO PASTE, CANNED	7,226	1,858
TOMATO SAUCE, CANNED	5,009	1,724
TOMATOES, CANNED		
Total Section 32 Type	102,949	\$39,367
SECTION 416-TYPE:		
BUTTER	52,618	49,158
BUTTER SOC	473	375
BUTTER OIL	173	284
CORNMEAL	7,729	980
Total Section 416 Type	60,992	\$50,797
Total Bonus Commodities	163,941	\$90,163
TOTAL - ALL COMMODITIES	1,050,951	\$663,985
CASH IN LIEU OF COMMODITIES	0	44,251
AMS/ASCS/PCIMS ADMIN. EXPENSES	0	2,396
GRAND TOTAL	1,050,951	\$710,632

Source: Preliminary food orders for school or fiscal year 1993.

Note: Due to rounding, the individual entries may not add to the totals shown.

31e-11

SCHOOL LUNCH PROGRAM
SCHOOLS, ENROLLMENT AND PARTICIPATION
FISCAL YEAR 1993

STATE OR TERRITORY	NUMBER OF SCHOOLS	ENROLLMENT (000)	PEAK PARTICIPATION (000)
Alabama	1,413	739	565
Alaska	379	103	45
Arizona	1,132	624	365
Arkansas	1,154	439	310
California	8,699	5,061	2,292
Colorado	1,421	577	295
Connecticut	1,011	458	226
Delaware	171	102	61
District of Columbia	179	80	47
Florida	2,728	1,979	1,174
Georgia	1,867	1,224	948
Hawaii	263	184	150
Idaho	531	219	140
Illinois	4,043	1,720	959
Indiana	2,202	984	602
Iowa	1,723	518	383
Kansas	1,674	473	316
Kentucky	1,573	683	521
Louisiana	1,773	823	691
Maine	736	210	106
Maryland	1,352	765	352
Massachusetts	2,079	854	441
Michigan	3,735	1,618	747
Minnesota	1,863	788	510
Mississippi	903	515	423
Missouri	2,462	884	562
Montana	501	149	87
Nebraska	963	275	203
Nevada	343	189	89
New Hampshire	478	179	87
New Jersey	2,586	1,541	505
New Mexico	755	323	183
New York	5,680	2,830	1,617
North Carolina	1,964	1,106	751
North Dakota	489	121	92
Ohio	4,034	1,836	943
Oklahoma	1,814	609	370
Oregon	1,298	480	250
Pennsylvania	3,673	1,768	985
Rhode Island	358	136	56
South Carolina	1,101	646	459
South Dakota	587	145	108
Tennessee	1,684	868	601
Texas	6,086	3,498	2,119
Utah	719	428	249
Vermont	341	100	49
Virginia	1,909	1,012	586
Washington	1,850	901	406
West Virginia	927	323	199
Wisconsin	2,351	840	487
Wyoming	390	99	58
American Samoa	0	0	0
Guam	44	34	21
North Mariana Island	0	0	0
Puerto Rico	2,724	731	486
Trust Territory (excluding NM)	0	0	0
Virgin Islands	60	44	18
Indian Tribe Set Asi	0	0	0
Indian Tribes	0	0	0
Freely Associated States	0	0	0
DDO/ Army/AF/USMC/Navy	172	89	39
TOTAL	92,947	43,925	25,334

NOTE: These data are based in part on preliminary data submitted by State and local agencies and are subject to change as revised reports are received. Totals may not add due to rounding.

31g-12

SCHOOL LUNCH PROGRAM
THOUSANDS OF LUNCHES SERVED
FISCAL YEAR 1993

STATE OR TERRITORY	TOTAL LUNCHES SERVED			
	PAID	REDUCED PRICE	FREE	TOTAL
Alabama	40,299	6,449	43,194	89,942
Alaska	3,131	742	3,207	7,080
Arizona	21,825	4,510	33,442	59,777
Arkansas	23,993	3,827	24,643	52,463
California	102,582	25,082	274,813	402,477
Colorado	24,923	3,960	17,894	46,777
Connecticut	19,855	2,496	14,040	36,391
Delaware	6,000	525	3,905	10,430
District of Columbia	853	309	6,572	7,734
Florida	70,762	14,793	114,408	199,963
Georgia	79,374	10,181	66,598	156,153
Hawaii	15,726	1,589	5,579	22,893
Idaho	12,458	2,384	7,571	22,413
Illinois	62,539	8,804	81,460	152,803
Indiana	65,250	5,279	29,188	99,717
Iowa	44,020	4,398	14,683	63,100
Kansas	30,913	4,351	14,948	50,412
Kentucky	40,523	5,725	35,573	81,821
Louisiana	40,205	7,474	61,051	108,731
Maine	8,758	1,521	6,677	16,956
Maryland	28,502	3,874	24,737	57,113
Massachusetts	38,858	3,374	27,298	69,531
Michigan	59,905	6,752	50,456	117,114
Minnesota	53,295	6,437	21,215	80,947
Mississippi	20,106	5,044	43,903	69,053
Missouri	50,912	5,650	32,896	89,458
Montana	7,720	1,309	5,183	14,212
Nebraska	20,747	3,084	8,715	32,546
Nevada	8,018	1,130	6,276	15,423
New Hampshire	10,234	1,034	3,486	14,754
New Jersey	43,655	6,534	42,313	92,502
New Mexico	8,171	2,811	18,422	29,403
New York	92,660	17,329	146,965	256,954
North Carolina	62,156	10,028	52,390	124,574
North Dakota	9,803	1,228	3,754	14,785
Ohio	84,193	8,897	60,915	154,004
Oklahoma	26,252	6,053	26,576	58,881
Oregon	20,474	3,431	16,083	39,987
Pennsylvania	90,092	10,699	59,311	160,101
Rhode Island	3,606	579	5,002	9,187
South Carolina	32,306	5,167	37,340	74,813
South Dakota	9,750	1,763	5,762	17,275
Tennessee	50,127	5,669	39,621	95,416
Texas	126,933	22,052	200,066	349,051
Utah	24,293	5,078	12,061	41,432
Vermont	4,318	554	2,538	7,411
Virginia	56,804	6,515	35,218	98,536
Washington	34,055	5,693	28,145	67,893
West Virginia	13,529	2,470	14,898	30,897
Wisconsin	49,224	5,408	23,898	78,529
Wyoming	5,718	865	2,746	9,329
American Samoa	0	0	0	0
Guam	2,219	178	929	3,325
North Mariana Island	0	0	0	0
Puerto Rico	4,972	5,067	57,079	67,119
Trust Territory (excluding NMJ)	0	0	0	0
Virgin Islands	760	420	1,735	2,915
Indian Tribe Set Asi	0	0	0	0
Indian Tribes	0	0	0	0
Freely Associated States	0	0	0	0
DOD Army/AF/USMC/Navy	4,315	864	906	6,085
Anticipated Adjustment	0	0	0	0
TOTAL	1,872,667	287,636	1,978,286	4,138,589

NOTE: These data are based in part on preliminary data submitted by State and local agencies and are subject to change as revised reports are received. Totals may not add due to rounding.

31g-13

SCHOOL BREAKFAST PROGRAM
SCHOOLS, ENROLLMENT, AND PARTICIPATION

FISCAL YEAR 1993

STATE OR TERRITORY	NUMBER OF SCHOOLS AND INSTITUTIONS	ENROLLMENT (000)	PEAK PARTICIPATION (000)
Alabama-----	970	469	126
Alaska-----	154	29	6
Arizona-----	881	503	101
Arkansas-----	1,049	390	108
California-----	4,469	2,975	645
Colorado-----	611	265	37
Connecticut-----	351	127	38
Delaware-----	151	90	12
District of Columbia-----	169	78	16
Florida-----	2,350	1,602	315
Georgia-----	1,329	802	236
Hawaii-----	236	164	26
Idaho-----	353	164	17
Illinois-----	1,674	810	145
Indiana-----	790	322	51
Iowa-----	1,035	232	35
Kansas-----	615	182	31
Kentucky-----	1,246	500	154
Louisiana-----	1,471	716	226
Maine-----	366	96	16
Maryland-----	957	490	58
Massachusetts-----	1,061	419	77
Michigan-----	870	316	60
Minnesota-----	859	377	48
Mississippi-----	710	474	158
Missouri-----	1,449	512	107
Montana-----	169	44	9
Nebraska-----	239	81	15
Nevada-----	244	144	19
New Hampshire-----	210	80	9
New Jersey-----	742	506	57
New Mexico-----	520	235	50
New York-----	3,680	1,782	328
North Carolina-----	1,707	1,098	201
North Dakota-----	148	38	7
Ohio-----	1,491	550	127
Oklahoma-----	1,321	173	107
Oregon-----	1,094	410	54
Pennsylvania-----	1,648	859	120
Rhode Island-----	119	41	6
South Carolina-----	861	463	138
South Dakota-----	275	47	13
Tennessee-----	1,403	699	164
Texas-----	5,836	3,372	674
Utah-----	247	226	16
Vermont-----	158	45	7
Virginia-----	1,423	610	126
Washington-----	1,391	638	76
West Virginia-----	913	321	87
Wisconsin-----	463	309	27
Wyoming-----	106	36	5
American Samoa-----	0	0	0
Guam-----	37	31	6
North Mariana Island-----	0	0	0
Puerto Rico-----	2,357	575	218
Trust Territory (excluding NMJ)-----	0	0	0
Virgin Islands-----	12	7	1
Indian Tribe Set Asi-----	0	0	0
Indian Tribes-----	0	0	0
Freely Associated States-----	0	0	0
DDO Army/AF/USMC/Navy-----	0	0	0
Anticipated Adjustment-----			
TOTAL-----	54,990	26,522	5,513

NOTE: These data are based in part on preliminary data submitted by State and local agencies and are subject to change as revised reports are received. Totals may not add due to rounding.

31g-14

SCHOOL BREAKFAST PROGRAM
THOUSANDS OF BREAKFASTS SERVED

FISCAL YEAR 1993

STATE OR TERRITORY	TOTAL BREAKFASTS SERVED					
	REDUCED PRICE			FREE		TOTAL
	PAID	REGULAR	SEVERE NEED	REGULAR	SEVERE NEED	
Alabama	2,534	1,015	126	12,939	3,668	20,281
Alaska	197	50	37	421	347	1,052
Arizona	1,667	374	520	4,247	10,240	17,048
Arkansas	3,059	809	276	9,423	4,370	17,937
California	5,635	767	2,592	14,258	89,808	113,060
Colorado	1,025	179	137	1,971	2,959	6,271
Connecticut	1,045	64	278	1,400	3,757	6,544
Delaware	318	36	43	654	1,076	2,128
District of Columbia	88	5	52	222	2,208	2,575
Florida	4,503	495	1,885	6,300	40,413	53,997
Georgia	6,568	1,012	1,508	9,631	20,325	39,044
Hawaii	1,515	341	0	2,205	11	4,072
Idaho	596	188	4	1,928	177	2,894
Illinois	2,077	804	0	21,755	19	24,655
Indiana	1,460	239	177	3,180	4,068	9,124
Iowa	1,739	251	170	1,846	2,151	6,158
Kansas	1,248	335	189	2,254	2,221	6,247
Kentucky	4,497	338	1,231	2,724	15,261	24,051
Louisiana	3,734	950	768	13,211	16,721	35,384
Maine	646	120	76	1,130	837	2,809
Maryland	983	182	412	1,537	6,515	9,628
Massachusetts	1,336	235	121	6,074	5,140	12,906
Michigan	1,099	57	273	673	8,995	11,097
Minnesota	1,292	328	163	2,707	3,544	8,035
Mississippi	2,306	1,322	44	21,025	473	25,169
Missouri	3,258	375	623	3,396	10,215	17,865
Montana	266	67	56	553	721	1,662
Nebraska	419	97	96	623	1,477	2,712
Nevada	696	64	102	771	1,794	3,406
New Hampshire	676	77	22	493	458	1,726
New Jersey	1,020	255	173	4,610	5,095	11,202
New Mexico	820	494	5	6,759	50	8,128
New York	5,838	641	2,312	5,071	44,623	58,484
North Carolina	4,600	818	1,515	7,709	18,925	33,567
North Dakota	441	59	30	481	390	1,401
Ohio	1,946	108	621	1,296	19,682	23,652
Oklahoma	2,867	743	869	4,668	8,182	17,329
Oregon	1,370	202	327	1,918	4,967	8,784
Pennsylvania	3,204	304	673	2,578	14,133	20,892
Rhode Island	63	16	0	1,154	35	1,268
South Carolina	2,952	260	1,080	2,503	15,732	22,527
South Dakota	325	112	75	646	1,365	2,523
Tennessee	4,824	1,000	564	10,142	9,383	25,912
Texas	12,138	2,034	2,990	24,270	68,127	109,559
Utah	434	98	156	462	1,673	2,823
Vermont	271	28	45	270	506	1,120
Virginia	4,495	1,349	96	15,106	1,097	22,143
Washington	1,552	278	405	3,264	7,718	13,217
West Virginia	3,175	149	800	1,144	7,893	13,160
Wisconsin	825	139	63	1,214	2,842	5,082
Wyoming	165	36	39	230	448	918
American Samoa	0	0	0	0	0	0
Guam	471	30	40	214	337	1,093
North Mariana Island	0	0	0	0	0	0
Puerto Rico	1,925	2,033	0	23,153	0	27,112
Trust Territory (excluding NMJ)	0	0	0	0	0	0
Virgin Islands	33	0	18	0	75	126
Indian Tribe Set Asi	0	0	0	0	0	0
Indian Tribes	0	0	0	0	0	0
Freely Associated States	0	0	0	0	0	0
DDO Army/AF/USMC/Nav	0	0	0	0	0	0
Anticipated Adjustment	0	0	0	0	0	0
TOTAL	112,235	22,340	24,926	268,411	493,247	921,158

NOTE: These data are based in part on preliminary data submitted by State and local agencies and are subject to change as revised reports are received. Totals may not add due to rounding.

31g-15

SUMMER FOOD SERVICE PROGRAM
NUMBER OF SITES, PARTICIPATION AND MEALS SERVED

FISCAL YEAR 1993

STATE OR TERRITORY	NUMBER OF SITES	PARTICIPATION (JULY) (000)	TOTAL MEALS SERVED (000)
Alabama	612	43	2,271
Alaska	4	0	5
Arizona	314	28	1,863
Arkansas	186	19	1,236
California	1,487	132	6,545
Colorado	145	15	756
Connecticut	252	21	1,067
Delaware	319	17	789
District of Columbia	39	6	198
Florida	1,511	165	8,299
Georgia	1,301	95	3,656
Hawaii	36	4	281
Idaho	23	1	301
Illinois	1,308	72	4,443
Indiana	209	15	868
Iowa	104	7	399
Kansas	73	7	461
Kentucky	359	24	1,195
Louisiana	374	57	2,932
Maine	59	3	333
Maryland	556	30	1,352
Massachusetts	439	26	1,035
Michigan	941	46	2,175
Minnesota	294	16	1,098
Mississippi	271	43	2,343
Missouri	379	25	1,547
Montana	46	4	190
Nebraska	86	6	280
Nevada	59	4	205
New Hampshire	50	2	178
New Jersey	1,125	66	3,416
New Mexico	604	56	2,707
New York	2,410	380	21,579
North Carolina	593	44	2,044
North Dakota	21	3	189
Ohio	625	37	2,127
Oklahoma	195	9	934
Oregon	160	10	579
Pennsylvania	1,952	105	6,912
Rhode Island	178	9	674
South Carolina	1,220	69	3,031
South Dakota	96	5	556
Tennessee	566	31	1,921
Texas	1,164	99	6,304
Utah	118	18	853
Vermont	42	2	79
Virginia	569	37	1,524
Washington	403	21	1,284
West Virginia	254	9	460
Wisconsin	251	18	930
Wyoming	17	1	56
American Samoa	0	0	0
Guam	0	0	0
North Mariana Island	0	0	0
Puerto Rico	1,046	89	2,590
Trust Territory (excluding NM)	0	0	0
Virgin Islands	119	5	188
Indian Tribe Set Asi	0	0	0
Indian Tribes	0	0	0
Freely Associated States	0	0	0
DD Army/AF/USMC/Navy	0	0	0
Anticipated adjustment	0	0	0
TOTAL	25,544	2,057	109,237

NOTE: These data are based in part on preliminary data submitted by State and local agencies and are subject to change as revised reports are received. Totals may not add due to rounding.

31g-16

CHILD AND ADULT CARE FOOD PROGRAM
PARTICIPATION AND MEALS SERVED

FISCAL YEAR 1993

STATE OR TERRITORY	NUMBER OF CENTERS HOMES	PARTICIP- ATION PEAK MONTH (000)	TOTAL MEALS SERVED						
			CHILD CARE AND ADULT CARE CENTERS					FAMILY DAY CARE HOMES (000)	TOTAL (000)
			PAID (000)	REDUCED PRICE (000)	FREE (000)	TOTAL (000)			
Alabama	2,770	30	1,770	461	9,350	11,581	9,984	21,566	
Alaska	761	7	1,417	214	498	2,130	1,780	3,910	
Arizona	3,427	34	4,342	1,391	8,552	9,921	23,506		
Arkansas	2,045	22	2,528	641	6,036	9,205	7,803	17,008	
California	25,369	240	11,905	6,013	35,178	53,097	91,742	144,839	
Colorado	5,375	42	4,389	837	4,192	9,417	17,121	26,539	
Connecticut	2,631	20	1,488	597	2,245	4,331	6,405	10,735	
Delaware	1,299	11	883	182	1,676	2,742	4,020	6,761	
District of Columbia	251	5	625	447	1,449	2,521	374	2,896	
Florida	3,609	65	4,265	1,660	27,127	33,052	7,070	40,122	
Georgia	3,085	40	1,645	745	8,529	10,920	11,113	22,033	
Hawaii	848	30	5,365	696	1,515	7,576	1,301	8,877	
Idaho	679	6	638	97	633	1,368	2,824	4,192	
Illinois	7,295	66	6,899	2,210	13,939	23,048	24,187	47,235	
Indiana	2,151	55	5,521	1,017	6,270	12,808	10,758	23,567	
Iowa	2,915	27	4,510	528	2,839	7,876	8,419	16,295	
Kansas	6,888	57	4,486	642	2,972	8,100	25,441	33,541	
Kentucky	1,444	35	6,882	1,260	8,662	16,803	2,391	19,195	
Louisiana	6,300	38	1,396	481	10,499	12,377	15,642	28,019	
Maine	1,669	13	642	167	1,102	1,910	6,928	8,838	
Maryland	5,179	33	3,596	485	4,855	8,936	15,373	24,309	
Massachusetts	7,438	48	3,014	1,316	8,460	12,790	18,887	31,677	
Michigan	8,449	69	5,319	1,169	8,938	15,426	28,290	43,716	
Minnesota	12,429	94	4,011	557	3,291	7,858	49,956	57,814	
Mississippi	2,301	35	966	571	12,517	14,053	5,492	19,544	
Missouri	3,062	42	4,229	833	9,923	11,985	15,367	27,332	
Montana	1,268	12	717	157	1,088	1,962	4,839	6,801	
Nebraska	3,768	35	3,458	339	2,933	6,729	15,258	21,987	
Nevada	539	5	613	185	632	1,429	1,719	3,148	
New Hampshire	477	6	1,081	208	696	1,986	1,386	3,372	
New Jersey	2,298	39	4,834	2,462	12,679	19,975	4,164	24,139	
New Mexico	5,682	38	2,724	707	4,437	7,868	14,353	22,222	
New York	7,264	135	8,889	4,299	40,279	53,466	15,643	69,108	
North Carolina	3,313	50	10,865	1,895	17,152	29,912	8,168	38,081	
North Dakota	2,318	19	918	123	693	1,735	8,773	10,508	
Ohio	7,228	81	9,506	1,459	12,096	23,061	21,236	44,297	
Oklahoma	2,386	35	4,418	873	9,982	15,273	6,589	21,862	
Oregon	4,236	28	2,024	286	2,399	4,709	13,380	18,089	
Pennsylvania	4,559	69	6,845	2,759	13,551	23,155	13,194	36,349	
Rhode Island	370	8	441	188	1,533	2,163	790	2,953	
South Carolina	1,252	22	1,300	771	6,583	8,655	4,498	13,153	
South Dakota	935	9	1,000	147	846	1,993	4,088	6,081	
Tennessee	1,854	32	2,563	696	8,733	11,993	6,945	18,938	
Texas	11,897	142	9,909	2,689	31,281	43,879	52,447	96,326	
Utah	4,066	36	4,143	587	3,775	8,504	15,242	23,746	
Vermont	960	8	413	101	438	952	3,099	4,051	
Virginia	4,085	32	3,891	861	4,455	9,206	11,004	20,210	
Washington	6,428	47	4,997	695	5,257	10,949	23,028	33,977	
West Virginia	1,339	10	1,873	181	2,415	4,469	2,669	7,137	
Wisconsin	4,244	47	6,541	700	4,881	12,121	11,249	23,370	
Wyoming	709	8	756	164	632	1,552	2,597	4,150	
American Samoa	0	0	0	0	0	0	0	0	
Guam	7	0	227	46	22	295	0	295	
North Mariana Island	0	0	0	0	0	0	0	0	
Puerto Rico	154	2	115	45	556	716	240	956	
Trust Territory (excluding NMJ)	0	0	0	0	0	0	0	0	
Virgin Islands	37	1	69	39	519	627	0	627	
Indian Tribe Set Asi	0	0	0	0	0	0	0	0	
Indian Tribes	0	0	0	0	0	0	0	0	
Freely Associated States	0	0	0	0	0	0	0	0	
DDO Army/AF/USMC/Navy	0	0	0	0	0	0	0	0	
Anticipated Adjustment	0	0	0	0	0	0	0	0	
TOTAL	203,322	2,119	187,859	48,878	388,791	625,528	664,467	1,289,995	

NOTE: These data are based in part on preliminary data submitted by State and local agencies and are subject to change as revised reports are received. Totals may not add due to rounding.

FOOD AND NUTRITION SERVICE

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

Special Milk Program:

For necessary expenses to carry out the special milk program, as authorized by section 3 of the Child Nutrition Act of 1966 (42 U.S.C. 1772), (\$20,277,000) \$18,089,000, to remain available through September 30, [1995] 1996. Only final reimbursement claims for milk submitted to State agencies within sixty days following the month for which the reimbursement is claimed shall be eligible for reimbursement from funds appropriated under this Act. States may receive program funds appropriated under this Act only if the final program operations report for such month is submitted to the Department within ninety days following that month. Exceptions to these claims or reports submission requirements may be made at the discretion of the Secretary.

This change makes the appropriation available until September 30, 1996.

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SPECIAL MILK PROGRAM

Appropriations Act, 1994	\$20,277,000
Budget Estimate, 1995	18,089,000
Decrease in Appropriation	-2,188,000

SUMMARY OF INCREASES AND DECREASES
(On basis of appropriation)

<u>Item of Change</u>	<u>1994</u> <u>Estimated</u>	<u>Program</u> <u>Change</u>	<u>1995</u> <u>Estimated</u>
Cash payments to States.....	\$20,277,000	-\$2,188,000	\$18,089,000

PROJECT STATEMENT
(On basis of appropriation)

<u>Project</u>	<u>1993</u> <u>Actual</u>	<u>1994</u> <u>Estimated</u>	<u>Increase or</u> <u>Decrease</u>	<u>1995</u> <u>Estimated</u>
1. Cash payments to States:				
(a) Paid milk (>130% poverty).....	\$13,750,854:	\$18,699,983:	-\$2,003,836:	\$16,696,147
(b) Free milk (<130% poverty).....	1,147,146:	1,577,017:	-184,164:	1,392,853
Total, Appropriation.....	14,898,000:	20,277,000:	-2,188,000:	18,089,000

PROJECT STATEMENT
(On basis of available funds)

<u>Project</u>	<u>1993</u> <u>Actual</u>	<u>1994</u> <u>Estimated</u>	<u>Increase or</u> <u>Decrease</u>	<u>1995</u> <u>Estimated</u>
1. Cash payments to States:				
(a) Paid milk (>130% poverty).....	\$17,637,732:	\$17,514,000:	+\$686,680:	\$18,200,680
(b) Free milk (<130% poverty).....	1,470,978:	1,477,000:	+45,000:	1,522,000
Total, obligations.....	19,108,710:	18,991,000:	+731,680:	19,722,680
Recovery of prior year obligations.....	-1,377,812:	—	—	—
Unobligated balances				
Available, start of year..	-5,379,187:	-347,680:	-1,286,000:	-1,633,680
Available, end of year....	347,680:	+1,633,680:	-1,633,680:	—
Expiring.....	2,198,609:			
Total, Available or Estimate.....	14,898,000:	20,277,000:	-2,188,000:	18,089,000

EXPLANATION OF PROGRAM

Overview of Program Development. Originally designed to support milk prices while encouraging children to drink more milk, the Special Milk Program was first funded by the Commodity Credit Corporation in 1955. The Agricultural Act of 1961 authorized the first direct appropriation for the Program. The Special Milk Program is now authorized by Section 3 of the Child Nutrition Act of 1966, as amended.

Eligibility. Eligible institutions include public and private nonprofit schools of high school grade or under, summer camps, and similar institutions that do not participate in another meal service program authorized by the Child Nutrition Act or the National School Lunch Act. In addition, children in split session kindergarten programs in public or private nonprofit schools who do not have access to the meal service programs operating in those schools may participate in the Special Milk Program.

Benefits. The program provides institutions with subsidies for half-pints of milk served to children. In Fiscal Year 1994, approximately 169 million half-pints of milk will be served in the Special Milk Program. These include about 158 million half-pints served to children whose family income is above 130 percent of poverty and about 10 million half-

pints served free to children whose family income is at or below 130 percent of poverty. During Fiscal Year 1994, the average full cost reimbursement for milk served to needy children is expected to be 14.38 cents for each half-pint. Milk served to non-needy children is estimated to be reimbursed at 11.06 cents for each half pint. The cash reimbursement rate for non-needy children is adjusted annually on July 1.

State/Federal Responsibilities. The program is operated through a partnership under agreements signed by State educational, social service or health agencies and the Food and Nutrition Service. State agencies administer the program through local school food authorities or other institutions. FNS provides cash reimbursements for milk served to eligible children and also provides funds for State administrative expenses relating to the program.

JUSTIFICATION OF INCREASES AND DECREASES

- (1) A decrease of \$2,188,000 is requested in the appropriation for the Special Milk Program (\$20,277,000 appropriated in 1994). On the basis of available funds, there is an increase of \$731,680 (\$18,991,000 available in 1994).

Need for change. The decrease in funds reflects the current estimate of funds needed to maintain the program in Fiscal Year 1995 due to adjustments for inflation and program participation.

Nature of change. An appropriation level of \$18,089,000 will be needed in Fiscal Year 1995 to provide reimbursement for milk served in the Special Milk Program. Participation continues to grow at a slow rate. Reimbursement rates for both paid and free milk are also expected to grow slowly in Fiscal Year 1995.

	<u>1993</u> <u>Estimate</u>	<u>1994</u> <u>Estimate</u>	<u>1995</u> <u>Estimate</u>
Half-pints served (thousands)			
Paid (above 130% of poverty)	156,787	158,355	159,938
Free 130% of poverty or below)	<u>10,167</u>	<u>10,269</u>	<u>10,371</u>
Total	<u>166,954</u>	<u>168,624</u>	<u>170,309</u>
Reimbursement Rates (cents)			
Paid	11.00	11.06	11.38
Free	14.20	14.38	14.68

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SPECIAL MILK PROGRAM

STATUS OF PROGRAM

The Special Milk Program, as authorized by section 3 of the Child Nutrition Act of 1966, helps schools and institutions not otherwise participating in a federally subsidized meal service program provide milk to children at a low price or free of charge in order to encourage children to drink more milk.

Program Operations. The program is administered in most States by the State educational agency. Where the States are prohibited by their laws from disbursing funds to private schools and institutions, or in instances where State agencies are unwilling to operate the program, the Food and Nutrition Service (FNS) administers the program directly through its regional offices. However, pursuant to P.L. 97-35, no State which administered the Special Milk Program for private schools and institutions since October 1980 may turn over administration of the program to FNS. During Fiscal Year 1993, FNS directly administered the Special Milk Program in seven States.

Program funds are made available to State agencies for use in providing payments to eligible outlets for milk served to children under the program. Participating schools and institutions that charge for any milk served under the program must agree to use the payments to reduce the cost of milk to the children. When local officials elect to serve free milk to needy children, the half-pint reimbursement rate for such milk is based on the average cost of all milk served in the eligible outlet under the program including local level distribution costs. All other milk served under the program is reimbursed at the per half-pint rate established annually by the Secretary. States also receive funds to offset the costs of administering the Special Milk Program from the Child Nutrition Programs appropriation.

For the period July 1, 1993 to June 30, 1994, the reimbursement rate for milk served to children from families with income above 130 percent of poverty is 11.0 cents per half-pint. During Fiscal Year 1993, the average reimbursement to cover the cost of milk in eligible outlets serving free milk to needy children at or below 130 percent of poverty, including local level distribution costs, was about 14.20 cents per half-pint.

During Fiscal Year 1993, the total number of half-pints served was 167 million including 156.8 million paid half-pints and 10.1 million free half-pints.

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SPECIAL MILK PROGRAM
NUMBER OF PARTICIPATING OUTLETS AND OBLIGATIONS BY STATE

FISCAL YEAR 1993

STATE OR TERRITORY	O U T L E T S					OBLIGATIONS 1/
	NON-RESIDENTIAL		SUMMER		TOTAL	
	SCHOOLS	CHILD CARE INSTITUTIONS	CAMPS			
Alabama	10	3	12	25	\$32,601	
Alaska	3	0	2	5	6,616	
Arizona	64	2	25	91	171,987	
Arkansas	6	0	9	15	25,025	
California	305	16	158	479	926,886	
Colorado	126	0	25	151	139,627	
Connecticut	309	2	28	339	552,837	
Delaware	25	0	0	25	43,965	
District of Columbia	8	0	0	8	16,622	
Florida	53	0	40	93	134,521	
Georgia	5	0	7	12	31,533	
Hawaii	3	0	2	5	6,735	
Idaho	141	0	42	183	195,297	
Illinois	961	6	59	1,026	2,852,973	
Indiana	224	0	47	271	358,787	
Iowa	53	15	75	143	228,017	
Kansas	355	0	9	364	219,066	
Kentucky	71	4	16	91	165,506	
Louisiana	12	0	11	23	69,363	
Maine	8	0	31	39	129,502	
Maryland	197	0	34	231	401,616	
Massachusetts	251	45	78	374	544,202	
Michigan	739	0	176	915	1,316,869	
Minnesota	490	74	111	675	1,046,210	
Mississippi	2	0	13	15	12,494	
Missouri	300	1	32	333	526,489	
Montana	76	0	10	86	61,942	
Nebraska	551	0	19	570	228,495	
Nevada	11	19	2	32	98,959	
New Hampshire	59	11	76	146	211,944	
New Jersey	349	0	0	349	1,135,453	
New Mexico	7	0	4	11	12,710	
New York	737	0	222	959	1,493,231	
North Carolina	55	0	32	87	123,285	
North Dakota	64	1	25	90	69,637	
Ohio	623	4	0	627	1,066,535	
Oklahoma	142	0	5	147	120,738	
Oregon	234	0	34	268	210,042	
Pennsylvania	634	15	108	757	801,730	
Rhode Island	118	1	10	129	113,287	
South Carolina	18	2	6	26	30,297	
South Dakota	30	0	7	37	46,503	
Tennessee	23	2	0	25	11,684	
Texas	29	1	32	62	117,105	
Utah	112	0	5	117	70,897	
Vermont	110	2	14	126	133,278	
Virginia	212	2	21	235	257,231	
Washington	108	0	64	172	276,953	
West Virginia	11	0	10	21	32,225	
Wisconsin	257	122	130	509	1,800,900	
Wyoming	10	2	11	23	18,803	
American Samoa	0	0	0	0	0	
Guam	0	0	0	0	0	
North Mariana Island	0	0	0	0	0	
Puerto Rico	0	0	0	0	0	
Trust Territory (excluding NM)	0	0	0	0	0	
Virgin Islands	3	0	0	3	4,390	
Indian Tribe Set Asi	0	0	0	0	0	
Indian Tribes	0	0	0	0	0	
Freely Associated States	0	0	0	0	0	
DDO Army/AF/USMC/Navy	0	0	0	0	0	
Anticipated Adjustment	0	0	0	0	0	
TOTAL	9,304	352	1,889	11,545	\$19,108,710	

1/ Obligations as reported September 30, 1993.

NOTE: These data are based in part on preliminary data submitted by State and local agencies and are subject to change as revised reports are received. Totals may not add due to rounding.

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SPECIAL MILK PROGRAM
HALF-PINTS OF MILK SERVED

FISCAL YEAR 1993

STATE OR TERRITORY	AVERAGE SERVED DAILY			TOTAL SERVED FY 93		
	FREE (000)	PAID (000)	TOTAL (000)	FREE (000)	PAID (000)	TOTAL (000)
Alabama-----	0	1	1	1	295	296
Alaska-----	0	0	0	0	50	50
Arizona-----	1	7	8	180	1,329	1,509
Arkansas-----	0	1	1	7	219	225
California-----	2	38	40	332	7,994	8,326
Colorado-----	0	5	6	61	1,190	1,251
Connecticut-----	2	23	25	417	4,482	4,899
Delaware-----	0	2	2	1	398	399
District of Columbia-----	0	1	1	2	148	150
Florida-----	0	6	6	8	1,212	1,220
Georgia-----	0	1	1	0	286	287
Hawaii-----	0	0	0	0	69	69
Idaho-----	0	8	8	85	1,664	1,750
Illinois-----	6	149	155	991	24,644	25,635
Indiana-----	2	14	16	277	2,900	3,178
Iowa-----	1	7	8	169	1,853	2,022
Kansas-----	2	11	12	235	1,685	1,920
Kentucky-----	7	1	8	160	1,297	1,456
Louisiana-----	0	3	3	0	631	631
Maine-----	1	4	5	206	909	1,115
Maryland-----	0	20	20	32	3,609	3,641
Massachusetts-----	2	20	22	340	4,504	4,844
Michigan-----	8	50	59	1,427	10,112	11,538
Minnesota-----	0	40	40	49	9,447	9,496
Mississippi-----	0	0	0	52	46	98
Missouri-----	1	23	24	186	4,544	4,730
Montana-----	0	3	3	77	463	540
Nebraska-----	2	9	11	310	1,673	1,983
Nevada-----	0	5	5	10	886	896
New Hampshire-----	0	5	6	45	1,868	1,913
New Jersey-----	5	50	55	871	9,187	10,058
New Mexico-----	0	0	1	14	98	111
New York-----	3	65	68	500	12,922	13,423
North Carolina-----	0	3	3	4	1,116	1,120
North Dakota-----	0	3	3	30	594	624
Ohio-----	5	46	51	740	8,731	9,471
Oklahoma-----	0	6	6	65	1,013	1,078
Oregon-----	1	7	9	187	1,666	1,853
Pennsylvania-----	4	30	34	690	6,389	7,079
Rhode Island-----	2	2	4	253	700	953
South Carolina-----	0	1	1	0	275	275
South Dakota-----	0	2	2	43	367	410
Tennessee-----	0	1	1	0	106	106
Texas-----	0	4	4	2	1,063	1,064
Utah-----	0	3	3	15	625	640
Vermont-----	1	6	7	164	998	1,162
Virginia-----	0	11	12	83	2,230	2,313
Washington-----	1	10	11	118	2,364	2,482
West Virginia-----	0	1	1	26	259	285
Wisconsin-----	4	78	82	682	15,482	16,165
Wyoming-----	0	1	1	0	171	171
American Samoa-----	0	0	0	0	0	0
Guam-----	0	0	0	0	0	0
North Mariana Island-----	0	0	0	0	0	0
Puerto Rico-----	0	0	0	8	0	0
Trust Territory (excluding NMJ)-----	0	0	0	0	0	0
Virgin Islands-----	0	0	0	20	14	34
Indian Tribe Set Asi-----	0	0	0	0	0	0
Indian Tribes-----	0	0	0	0	0	0
Freely Associated States-----	0	0	0	0	0	0
DDO Army/AF/USMC/Navy-----	0	0	0	0	0	0
Anticipated Adjustment-----	0	0	0	0	0	0
TOTAL-----	61	792	853	10,167	156,787	166,954

NOTE: These data are based in part on preliminary data submitted by State and local agencies and are subject to change as revised reports are received. Totals may not add due to rounding.

FOOD AND NUTRITION SERVICE

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

Special Supplemental Food Program for Women, Infants, and Children (WIC):

- For necessary expenses to carry out the special supplemental food program as authorized by section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786),
- 1 [\$3,210,000,000 } \$3,563,588,000 to remain available through September 30, [1995] 1996 of which up to \$5,500,000 may be used to carry out the farmers' market coupon program. Provided, That none of the funds in this Act shall be available to pay administrative expenses of WIC clinics except those that have
 - 2 an announced policy of prohibiting smoking within the space used to carry out the program (: Provided further, That until revised allocation regulations have been issued, the Secretary may waive the 15 percent cap regulation to ensure that all funds are allocated to States most in need): Provided further, That no State will incur an interest liability to the Federal Government on WIC rebate funds provided that all interest earned by the State on these funds is used for program purposes.

The first change makes the appropriation available until September 30, 1996.

The second change deletes language waiving the 15 percent cap regulation because regulatory revisions will be completed during Fiscal Year 1994.

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SPECIAL SUPPLEMENTAL FOOD PROGRAM FOR WOMEN, INFANTS, AND CHILDREN (WIC)

Appropriations Act, 1994.....	\$3,210,000,000
Budget Estimate, 1995	<u>3,563,588,000</u>
Increase in Appropriation	<u>+353,588,000</u>

SUMMARY OF INCREASES AND DECREASES
(On basis of adjusted appropriation)

<u>Item of Change</u>	<u>1994 Estimated</u>	<u>Program Changes</u>	<u>1995 Estimated</u>
Special Supplemental Food Program (WIC)	\$3,210,000,000	+\$353,588,000	\$3,563,588,000

PROJECT STATEMENT
(On basis of adjusted appropriation)

<u>Project</u>	<u>1993 Actual</u>	<u>1994 Estimated</u>	<u>Increase or Decrease</u>	<u>1995 Estimated</u>
Special Supplemental Food Program (WIC)				
(a) Grants to States for supplemental food:	\$2,145,764,000	\$2,407,677,000	+\$241,697,000	\$2,651,874,000
(b) Costs for nutrition services and administration.....	706,236,000	791,823,000	+110,896,000	902,719,000
(c) Farmers' Market Coupon Program.....	3,000,000	5,500,000	--	5,500,000
(d) Program evaluation projects.....	5,000,000	5,000,000	-1,505,000	3,495,000
Total, Available or Estimate.....	<u>2,860,000,000</u>	<u>3,210,000,000</u>	<u>353,588,000</u>	<u>3,563,588,000</u>

PROJECT STATEMENT
(On basis of available funds)

<u>Project</u>	<u>1993 Actual</u>	<u>1994 Estimated</u>	<u>Increase or Decrease</u>	<u>1995 Estimated</u>
Special Supplemental Food Program (WIC):				
(a) Grants to States for Supplemental food.....	\$2,190,181,595	\$2,468,560,982	+\$274,578,018	\$2,743,139,000
Costs for nutrition svcs and administration.....	730,060,532	851,228,000	+80,226,000	931,454,000
(c) Farmers' Market Coupon Program.....	3,249,822	5,500,000	--	5,500,000
(d) Program evaluation projects.....	4,711,023	5,000,000	-1,505,000	3,495,000
TOTAL, Obligations.....	<u>2,928,202,972</u>	<u>3,330,288,982</u>	<u>+353,299,018</u>	<u>3,683,588,000</u>
Recovery of prior obligations.....	-66,641,958	-120,000,000	--	-120,000,000
Unobligated balances.....				
Avail. start of year.....	-2,647,148	-288,982	+288,982	--
Avail., end of year.....	288,982		--	--
Expiring.....	797,152	--	--	--
Total, Available or Estimate.....	<u>2,860,000,000</u>	<u>3,210,000,000</u>	<u>+353,588,000</u>	<u>3,563,588,000</u>

EXPLANATION OF PROGRAM

Overview of Program Development. The Special Supplemental Food Program for Women, Infants and Children (WIC) is authorized by section 17 of the Child Nutrition Act of 1966, as amended. The program was established as a two-year pilot project under Public Law 92-433. Public Law 96-499, enacted on December 5, 1980, extended the program authorization through September 30, 1984. The authorization was extended through 1989 by Public Laws 99-500 and 99-591, the School Lunch and Child Nutrition Amendments of 1986. Public Law 101-147, the Child Nutrition and WIC Reauthorization Act of 1989, authorizes the program through September 30, 1994.

Eligibility. Funds are made available to local health clinics or other service sites through State departments of health and to Indian Tribal Organizations to provide supplemental foods to low-income pregnant, postpartum and breastfeeding women, to infants, and to children up to five years of age who are determined by competent professionals (physicians, nutritionists, nurses and other health officials) to be at nutritional risk.

Benefits. The WIC Program is intended to promote good health among mothers and their children by encouraging breastfeeding, providing nutrition education and referrals to health services, and supplementing recipients' existing diets with food packages designed to provide foods rich in nutrients often lacking in the diets of the WIC Program target population. The authorized supplemental foods are iron-fortified infant formula, infant cereal, milk, cheese, eggs, iron-fortified breakfast cereal, fruit or vegetable juice which contains vitamin C, dry beans and peas, and peanut butter. For women who exclusively breastfeed, a special package is available which includes increased quantities of certain WIC foods as well as tuna and carrots.

The WIC program encourages breastfeeding in an effort to raise breastfeeding rates toward the U.S. Surgeon General's goal, which is to increase to at least seventy five percent the proportion of mothers who breastfeed their babies in the early postpartum period and to at least fifty percent the proportion who continue breastfeeding until their babies are 5 to 6 months old. USDA has added an enhanced food package offering more types and quantities of foods to women who breastfeed their infants and receive no infant formula through the WIC Program.

There are three general types of delivery systems for WIC foods: (1) retail purchase in which participants obtain supplemental foods through retail stores; (2) home delivery systems in which food is delivered to the participant's home; and (3) direct distribution systems in which participants pick up food from a distribution outlet. WIC benefits are free of charge to all participants. Expansion of cost containment measures, especially infant formula rebates, and increases in appropriated funds have allowed the number of people who can be served by the program to increase.

State/Federal Responsibilities. The program is administered in a Federal/State partnership in which FNS provides cash grants to States for food and administrative expenses. States develop operating plans which, after consideration of public comment and FNS approval as required by statute and Federal regulations, define how the State will implement the program for the year. States then enter into written agreements with local agencies and allocate administrative money to local health care agencies and clinics where WIC programs are administered. In retail purchase States, the local clinics prescribe food packages by providing participants "food instruments" each month which the participants exchange for foods at approved retail grocery stores. The form of the food instruments varies from State to State; they may be vouchers or checks. Where food instruments are checks, retailers deposit them in a bank before their expiration date. Vouchers must be submitted to a State or local WIC agency before their expiration date and the retailers are paid within 60 days. The States are responsible for monitoring retailers and assuring the integrity of the redemption system. Presently, approximately 45,500 retailers are authorized to participate in the program.

FNS provides funds for the cost of the food packages and the costs of administering the program, including nutrition education and health care referrals. Food funds are allocated to States for food costs on the basis of a funding formula which takes into consideration previous funding, benefit targeting, inflation and each state's number of income eligible persons, low weight births, and infant mortality rates. Administrative funds are allocated among the States for costs for nutrition services and administrative costs associated with the WIC Program. These costs include certifying participant eligibility, food delivery and warehousing, monitoring, nutrition education, breastfeeding promotion, health care coordination and referral, drug abuse education, financial management, systems development and operations, clinic operations and administration by State agencies. Slightly more than one-sixth of these administrative funds must be used for breastfeeding

promotion and support and nutrition education activities. Up to one-half of one percent of sums appropriated, not to exceed \$5 million, may be made available for evaluation of program performance.

State Food Cost Containment Initiatives to Expand Participation. The Commodity Distribution Reform Act and WIC Amendments of 1987, P.L. 100-237, the Rural Development, Agriculture and Related Agencies Appropriations Act of 1989, P.L. 100-460, and the Child Nutrition and WIC Amendments Reauthorization Act, P.L. 101-147, require State agencies with retail food delivery systems to use a single supplier competitive bidding system or a system with equal savings for the procurement of infant formula. Savings from these efforts are to be used to expand program participation. Further, since increasing participation would increase administrative costs, P.L. 101-147 authorized administrative funding based on a per participant allocation, annually adjusted for the increased costs of providing State and local services.

The projected total amount of savings from rebates for Fiscal Year 1994 is estimated at about \$930 million, supporting an average of 1.5 million participants each month. For Fiscal Year 1995, savings are projected at over \$950 million, and will support about 1.5 million participants each month.

Farmers' Market Coupon Program. The Hunger Prevention Act of 1988, P.L. 100-435, authorized FNS to award grant funds for up to ten three-year demonstration projects to provide WIC participants with coupons that can be redeemed for fresh, unprepared foods at authorized farmers' markets. The following States were selected through a competitive grant application process to administer the projects: Connecticut, Iowa, Maryland, Massachusetts, Michigan, New York, Pennsylvania, Texas, Vermont, and Washington. A permanent WIC Farmers' Market Coupon Program (FMCP) which allows additional States to participate in the program, subject to appropriation, was authorized by the WIC Farmers' Market Nutrition Act of 1992, Public Law 102-314, enacted on July 2, 1992. The FMCP grandfathers in the States which participated in the earlier demonstration project. In Fiscal Year 1993, North Carolina began operations as the newest FMCP State agency. In Fiscal Year 1994, \$5.5 million will be allocated to current States and new approved States. First priority is to fund current States at their Fiscal Year 1993 levels. Remaining funds will be divided between current States for expansion and new States.

JUSTIFICATION OF INCREASES AND DECREASES

- (1) An increase of \$353,588,000 in the appropriation for WIC (\$3,210,000,000 appropriated in 1994).

Need for Change. This estimate continues to work toward full funding in WIC within the population currently estimated to be eligible for WIC. This request will fund inflationary increases for food and administrative costs while increasing average monthly participation by 700,000 additional at-risk pregnant women, infants and children. The request is \$353.6 million above the 1994 appropriation of \$3.21 billion. About \$247.0 million of the increase will support new participation, and the remaining \$108.1 million will cover projected food and administrative cost increases for existing participants. The popular Farmers' Market continues at \$5.5 million. Program Evaluation projects decrease by \$1.5 million because the Child Impact Study is no longer being done.

Nature of Change. The average monthly cost per person will rise from \$40.95 in Fiscal Year 1994 to \$42.38 in Fiscal Year 1995. Program participation will rise from 6.5 million in Fiscal Year 1994 to 7.2 million persons per month in Fiscal Year 1995.

Special Supplemental Food Program for Women, Infants and Children, (WIC)

	1993 <u>Actual</u>	1994 <u>Estimate</u>	1995 <u>Estimate</u>	<u>Change</u>
Average Participation per month (in millions)1/...	5.9	6.5	7.2	+0.7
Average Cost per person per month				
Food Costs.....	\$29.82	\$30.45	\$31.63	+\$1.18
Administrative Cost.....	10.18	10.50	10.75	+.25
Total	\$40.00	\$40.95	\$42.38	+\$1.43

- 1/ A portion of the estimated participation is supported by anticipated recoveries from the previous fiscal year.

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Special Supplemental Food Program
for Women, Infants and Children, (WIC)

	1993 <u>Actual</u>	1994 <u>Estimate</u>	1995 <u>Estimate</u>	<u>Change</u>
Program level (\$ in millions):				
Food Costs.....	\$2,190.2	\$2,468.6	\$2,740.6	+\$361.3
State and local administrative costs.....	730.1	851.2	931.5	+111.0
Farmer's Market Coupon Program.....	3.2	5.5	5.5	--
Program evaluation projects	4.7	5.0	3.5	-1.5
Total 2/.....	\$2,928.2	\$3,330.3	\$3,683.6	+\$353.3

2/ Includes estimated recoveries and reallocated funds.

SPECIAL SUPPLEMENTAL FOOD PROGRAM FOR WOMEN, INFANTS AND
CHILDREN (WIC)

STATUS OF PROGRAM

The Special Supplemental Food Program for Women, Infants and Children (WIC) provides nutritious supplemental foods to low income pregnant, postpartum, and breastfeeding women, to infants, and to children up to their fifth birthday, who are determined by competent professionals (physicians, nutritionists, nurses, and other health officials) to be at nutritional risk.

The Food and Nutrition Service makes funds available to participating State agencies which in turn distribute the funds to participating local agencies. Participating State agencies may be State health departments or Indian tribes which are recognized by either the Department of Health and Human Services' Indian Health Service or by the Department of the Interior. State and local agencies use WIC funds to pay the costs of specified supplemental foods provided to WIC participants, and to pay specified administrative costs, including the cost of nutrition education, breast feeding promotion, and health care referrals.

Program Participation and Costs

An average of 5.9 million persons participated each month in Fiscal Year 1993. The monthly costs of the food package varied among the individual States, with an average monthly cost of \$29.82 nationwide. In addition to food costs, approximately 25 percent of the funds appropriated were available for State program administrative costs. In Fiscal Year 1993, these costs averaged \$10.18 per person per month for a total monthly cost per person of \$40.00.

Benefit Targeting

During Fiscal Year 1993, State agencies continued reporting nutritional risk priority data on participants. This data provides information on the results of State agency targeting efforts. Strong emphasis has been placed on service to high risk persons. High risk persons are placed in Priorities I - III, and are considered to be most in need of the WIC program benefits due to nutrition-related medical conditions. The Priority I group consists of pregnant and breastfeeding women and infants with certain medical conditions. Priority II consists of infants of women who actually participated in WIC or infants of women who would have been eligible to participate as Priority I participants during their pregnancies. Also, women who are breastfeeding Priority II infants may be classified as Priority II. Priority III is composed of children with certain medical conditions and some high-risk postpartum women. Analysis of the priority data collected for July 1992 - June 1993 disclosed that Priorities I, II and III account for 30.50, 15.27 and 37.17 percent, respectively, of the national WIC caseload. Thus, over 82 percent of all persons enrolled in WIC are in the three highest risk groups.

Cost Containment Initiatives

General. In an effort to use their food grants more efficiently, all geographic WIC State agencies and most Indian Tribal State agencies have implemented cost containment activities. Savings generated by competitive bidding, rebate, home delivery or direct distribution systems allow State agencies to provide benefits to more participants at no additional food cost. The most successful cost containment strategy has been to obtain rebates on infant formula. By the end of Fiscal Year 1993, 75 State agencies had contracts with infant formula companies to receive rebates for each can of infant formula purchased with WIC funds. Rebate savings to these State agencies for Fiscal Year 1993 are projected to be over \$820 million.

Cost Containment Statutes. The Child Nutrition and WIC Reauthorization Act of 1989, enacted November 10, 1989, codified the provisions of Public Law 100-460 (an appropriations act which expired September 30, 1989) which required WIC State agencies to explore the feasibility of implementing one of four acceptable cost containment initiatives: competitive bidding, rebates, home delivery, or direct distribution. Such cost containment initiatives were to focus primarily on the acquisition of infant formula, and on other foods supplied by the WIC Program, if practicable. It also required most WIC State agencies with retail purchase food delivery systems to pursue and implement competitively bid single source infant formula rebate contracts, unless a State agency can demonstrate to FNS' satisfaction that an alternative arrangement will produce equal or greater food cost savings. On October 24, 1992, Public Law 102-512, the Infant Formula Procurement Act, was signed. This legislation amends the Child Nutrition Act of 1966 to enhance competition among infant formula manufacturers for the WIC Program. The major provisions of this act are that (1) the U.S. Department of Agriculture, Food and Nutrition Service staff will conduct bid solicitation/selection for multi-State (two or more States) infant formula rebate contracts; and (2) to disqualify and/or impose civil penalties of up to \$100 million per year for infant formula manufacturers that price-fix or engage in related anti-competitive activities. The WIC Program currently has seven multi-State infant formula rebate contracts, involving 27 WIC geographic State agencies and three WIC Indian State agencies.

Cost Containment in the National Performance Review. The Vice President's Task Force Report on the National Performance Review concluded that additional efforts beyond those employed to achieve infant formula rebates to contain costs in WIC could result in savings of millions of dollars, and that all savings should be used by the Program to increase participation among low income and nutritionally vulnerable children. The report recommended that the Federal Government assume stronger leadership in expanding cost containment efforts, particularly in encouraging States to seek rebates on additional items in the WIC food package such as infant cereal, juice, and adult food products; and in encouraging States to seek savings through better food package size and brand name management practices. Since infant formula accounts for about 26 percent of the shelf price of WIC foods, after adjusting for rebates, there could be potential savings from better food package management and other rebate contracts. The other 74 percent consists of: milk 25 percent, juice 16 percent, cheese 13 percent, cereal 13 percent, eggs 4 percent, and peanut butter/dried beans 3 percent. The report also encourage States to be more effective at promoting breastfeeding in the interest of public health. The National Performance Review recommendations were examined and efforts to take them into account continued to be emphasized.

WIC Vendor Management

During Fiscal Year 1988, the Office of the Inspector General (OIG) performed a national audit of WIC State agency vendor monitoring systems, vendor compliance activities, the reconciliation process, efforts to detect and prevent dual participation, and overall FNS/State agency monitoring. The major findings of the audit dealt with (1) the inadequacy of State agency ADP systems to detect and analyze vendor redemption data for probable abuse; (2) weak State agency vendor selection practices; (3) limited Federal staff resources to oversee State agency operations; (4) the need to standardize vendor sanctions nationwide; and (5) the need for improved information sharing on vendor abuse between the Food Stamp and WIC Programs.

The corrective action plan developed in response to the audit has resulted in the initiation of several projects. The Vendor Futures Group, consisting of regional, headquarters, and State representatives was convened to discuss proposed regulations addressing the deficiencies found in the audit. A National Vendor Meeting was held in December 1988 to provide technical assistance to States on identifying and taking action against abusive vendors. An FNS Instruction was developed and distributed in December 1988 to facilitate the sharing of information between State agencies and FNS on joint WIC/Food Stamp vendors. A Vendor Management Analysis Profile reporting system was established to report on State actions against abusive vendors.

Proposed regulations addressing the deficiencies outlined in the audit were discussed at the February 1990 meeting of the National Association of WIC State Directors. The proposed rule was published December 28, 1990. Over 1,000 comments were received on the proposal. A final rule is expected to be published during calendar year 1994. A national comprehensive management evaluation guide to ensure a uniform approach to review of State agency operational areas has been developed as well as a format for improved reporting of State agency vendor management data to FNS. In addition, a Vendor Management meeting was held in June 1993 to allow States to discuss issues and practices in vendor management.

During Spring 1993, the Vendor Issues Study was issued. This study presents the results of an investigation into the extent of vendor overcharging and other vendor abuses in the WIC Program retail distribution system.

This study was the first to investigate the magnitude and incidence of such fraud and abuse on a national scale. The primary focus of this study was overcharging or undercharging on safe buys. A safe buy is defined as one in which the purchaser buys all of the food specified on the WIC food instrument in the maximum amounts provided. Vendor response to a non-WIC food substitution was also studied, but trafficking and many other forms of abuse were not investigated.

The results, extrapolated to the retail vendor population from which the sample was drawn, suggest that approximately 22 percent of vendors overcharge for WIC foods on one or more of three safe buys. The aggregate loss due to overcharging for safe buys is about \$39.5 million, or 1.9 percent of estimated annual retail redemptions. This is substantially less than the amount suggested by previous OIG reports. Overcharging was found to be more common among stores with less than six registers and when purchases were done with women and child food instruments.

Undercharging occurred at a high enough level (\$11.7 million or 0.6 percent of annual retail redemptions; 39 percent of the estimated overcharging) that it may be more than a random event, but analyses did not show any significant explanation for undercharging.

WIC Program Research

Agency research priorities for Fiscal Year 1993 included the development of a WIC Inflation Index to be used to estimate WIC participation and to monitor WIC food prices. The Index final report is nearing completion and will be sent to Congress in Fiscal Year 1994. The Agency also continued work on comparative analyses of WIC participants and nonparticipants health care use, breastfeeding patterns, and birth outcomes using data from the 1988 National Maternal and Infant Health Survey (NMIHS), state-by-state estimates of WIC eligibles using Current Population Survey (CPS) data, and

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measurement of vendor abuse, was released in May 1993. In addition, the Agency continued work on the congressionally-mandated, biennial reports on WIC Participant and Program characteristics (PC).

Studies initiated during Fiscal Year 1993 include:

- o Services Integration Study. This study is designed to describe low-income, pregnant women's participation in Federal and private assistance programs. The study will investigate local service network characteristics that promote pregnant and postpartum women's participation in programs for which they are eligible.
- o WIC Infant Feeding Practices Study. The goal of this study is to obtain information about the infant feeding practices of WIC participants. The study will examine pre- and postnatal influences on WIC mother's infant feeding practices; describe how foods in the WIC package are being used; and identify WIC mother's attitudes and practices relative to the initiation and continuation of breastfeeding. The study will also identify potential barriers to the initiation and continuation of breastfeeding.

An Examination of An Alternative WIC Food Cost Inflation Index

In the language accompanying the Fiscal Year 1991 WIC appropriation, Congress directed the Department to develop an inflation index for use in adjusting the WIC allocations based on foods prescribed in the WIC food package. Since 1986, FNS has used the Thrifty Food Plan (TFP) cost index to project WIC food cost inflation and to compute the inflation factor in the State funding formula. The TFP is a low-cost food plan consisting of 31 food groups designed to meet the nutritional needs of low-income families and serves as the basis for determining the value of food stamp benefits. The WIC food package, however, is much smaller than either the TFP or the CPI, consisting of only eight food items, and is weighted heavily towards milk, eggs, cheese, and infant formula, together comprising over two thirds of the WIC package. In recent years, TFP cost inflation has not tracked actual WIC food cost inflation. FNS issued an interim report in August 1992 presenting the proposed index and soliciting public comments. During Fiscal Year 1993, FNS reviewed all comments received from the public, performed additional tests on the WIC index, and began developing the final report. The Department will send the final report containing its findings and recommendations to Congress in Fiscal Year 1994.

WIC Farmers' Market Nutrition Program

P.L. 102-314, enacted on July 2, 1992 transformed the Farmers' Market Coupon Demonstration Project (FMCDP) into the WIC Farmers' Market Nutrition Program (FMNP). The Fiscal Year 1993 appropriation for the program was \$3 million. The following States currently administer the program: Connecticut, Iowa, Maryland, Massachusetts, Michigan, New York, North Carolina, Pennsylvania, Texas, Vermont, and Washington. Seven of the projects are administered by State Departments of Agriculture and four (Texas, North Carolina, Michigan and Washington) are administered by State Departments of Health.

Immunization Promotion

FNS, the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (DHHS) are working together to increase access to immunization services through the WIC Program. Since June 1990, State WIC Directors have been strongly encouraged to establish regular liaison and ongoing coordination with their State Immunization Program Managers. Emphasis in this area is appropriate for the WIC Program given its mandate to function as an adjunct to health care services and WIC's effective role as a "gateway" program for important maternal and child health benefits. The WIC Program has regulatory responsibility to coordinate with immunization services. Many local agencies are located on-site with health care services where immunizations are available. Others refer participants to other health care services available in the community for immunization.

Drug Abuse Prevention

The Anti-Drug Abuse Act of 1988 (P.L. 100-690), and the Child Nutrition and WIC Reauthorization Act of 1989 (P.L. 101-147), expanded the role of the WIC Program by adding drug abuse prevention information and referral activities. For the WIC Program, P.L. 100-690 defines drug abuse education as: the provision of information concerning the dangers of drug abuse; the referral of participants who are suspected drug abusers to drug abuse clinics, treatment programs, counselors, or other drug abuse professionals; and the provision of materials developed by the Secretary. Congress directed USDA to conduct a study with respect to the appropriate methods of drug abuse education in the WIC Program. This study was published and copies were sent to Congress in January 1990. Findings from this study and advice of both governmental and private drug abuse prevention experts were being used to define the role WIC should and is able to play in providing drug abuse information and referrals. FNS has established a continuing dialogue with DHHS' Office for Substance Abuse Prevention to collaborate on establishing policies and designing materials.

A final rule implementing the mandates of P.L. 100-690 and P.L. 101-147 was published in February 1993. A brochure in English and Spanish, warning participants about the dangers of alcohol and other drug use during pregnancy and breastfeeding, were distributed to WIC State agencies in January

1991. FNS developed a resource manual and videotape, which were made available in Fiscal Year 1992, to assist local agency staff in meeting the drug abuse information and referral requirements. The videotape has a companion piece which outlines effective interviewing, screening and referral techniques. FNS also developed a videotape for participants. It has a companion leader's guide for WIC professionals to use in counseling participants.

Breastfeeding Promotion Efforts

The WIC program promotes breastfeeding as the best form of nutrition for infants through the provision of support and encouragement to new mothers and through nutrition education during pregnancy. In addition, breastfeeding WIC mothers receive a larger food package and, if otherwise eligible, are able to stay on WIC for a longer period of time than non-breastfeeding postpartum women. By law, States are required to expend at least \$8 million of WIC administrative funding for breastfeeding promotion and support; each State is required to spend its proportionate share. Many States spend more than their minimum requirements on this effort. USDA has numerous special initiatives under way to promote breastfeeding.

The WIC program's goal for breastfeeding is the Surgeon General's Healthy People 2000 goal to increase to at least 75 percent the proportion of mothers who breastfeed their babies in the early postpartum period and to at least 50 percent the proportion who continue breastfeeding until their babies are 5 to 6 months old. The baseline used in the Healthy People 2000 publication for low income women is based on data collected in Ross Laboratories Mothers Survey in 1988. They found 32 percent of low income mothers breastfeeding in the early postpartum period and 9 percent breastfeeding at 5 to 6 months. Using the 1988 National Maternal and Infant Health Survey, and FNS funded analysis found that 37.7 percent of Prenatal WIC participants breastfeed their infants as compared to 44.4 percent of income eligible non-participants. The mean duration of breastfeeding for prenatal WIC participants was 1.19 months as compared to 1.63 months for the income eligible non-participants.

Currently the WIC program has no required collection of data on breastfeeding rates. A 1989 National Association of WIC Directors (NAWD) survey found that 56 percent of the States had methods in place to track breastfeeding rates among WIC participants. Variation in definition and other factors made it impossible to calculate comparable rates among States. Data on breastfeeding rates is currently collected as part of the biennial WIC Participant and Program Characteristics study. However, this data is provided only to the extent that it is available on State management information systems. Less than 25 percent of States reported this information in 1992.

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SPECIAL SUPPLEMENTAL FOOD PROGRAM (WIC)
PARTICIPATION AND PROGRAM FINANCING
FISCAL YEAR 1993

STATE OR TERRITORY	NUMBER OF CLINICS PROVIDING BENEFITS 2/	AVERAGE MONTHLY PARTICIPATION				PROGRAM GRANT (000)
		WOMEN	INFANTS	CHILDREN	TOTAL	
Alabama	120	27,481	36,308	56,973	120,762	\$60,365
Alaska	212	3,206	3,622	5,169	11,997	9,081
Arizona 1/	152	23,451	29,094	37,946	90,491	50,852
Arkansas	124	20,204	23,637	39,678	83,519	37,426
California	556	226,892	254,560	177,014	658,466	327,439
Colorado 1/	119	13,432	13,903	31,474	58,809	29,151
Connecticut	81	10,450	13,519	41,670	65,639	34,770
Delaware	26	3,043	4,241	7,832	15,116	7,335
District of Columbia	16	3,383	5,616	7,091	16,090	8,583
Florida 1/	258	58,292	72,565	128,163	259,020	116,109
Georgia	275	34,300	55,945	105,609	195,854	89,299
Hawaii	15	5,446	6,667	10,030	22,143	16,912
Idaho	64	7,095	8,000	15,503	30,598	17,514
Illinois	248	38,768	71,874	103,694	214,336	112,870
Indiana	161	31,946	40,024	65,047	137,017	60,110
Iowa	139	11,931	12,080	33,211	57,222	26,318
Kansas	148	11,685	13,790	26,859	52,334	25,352
Kentucky	151	25,491	28,922	55,270	109,683	52,599
Louisiana	120	29,859	33,705	60,799	124,363	70,797
Maine 1/	113	5,757	6,422	14,558	26,737	13,244
Maryland	108	19,558	24,538	36,757	80,853	37,625
Massachusetts	107	22,903	27,239	52,137	102,279	46,300
Michigan	252	38,599	52,992	96,027	187,618	91,211
Minnesota	263	14,560	19,960	52,642	87,162	39,107
Mississippi 1/	141	22,080	30,364	54,849	107,293	45,668
Missouri	263	28,831	31,933	51,029	111,793	56,563
Montana	82	3,243	4,325	11,292	18,860	10,521
Nebraska 1/	113	7,179	8,060	17,354	32,593	15,997
Nevada 1/	47	5,667	6,433	9,402	21,502	10,608
New Hampshire	186	3,758	4,618	10,846	19,222	9,593
New Jersey	457	25,052	34,644	69,422	129,118	62,290
New Mexico 1/	113	10,063	13,159	24,995	48,217	24,962
New York 1/	563	74,654	113,915	215,073	403,642	210,464
North Carolina 1/	191	41,184	49,999	77,862	169,045	77,419
North Dakota 1/	104	3,782	3,860	10,878	18,520	9,476
Ohio	294	51,449	70,295	112,460	243,204	113,521
Oklahoma 1/	179	18,897	22,997	39,546	81,440	42,495
Oregon	113	17,650	14,749	31,465	63,864	29,597
Pennsylvania	399	37,118	53,794	142,160	233,080	113,061
Rhode Island	23	3,232	4,832	9,980	19,044	10,708
South Carolina	135	27,649	32,782	48,337	108,768	54,752
South Dakota 1/	96	4,926	5,280	12,448	22,654	12,032
Tennessee	154	30,660	50,857	39,393	120,910	60,115
Texas	610	130,186	143,926	267,835	541,947	237,495
Utah	65	12,392	14,131	27,154	53,677	25,932
Vermont	61	3,430	2,997	9,794	16,221	8,536
Virginia	156	24,589	31,519	63,365	119,473	56,441
Washington	220	24,259	31,652	24,942	80,853	44,322
West Virginia	69	8,119	12,381	22,859	43,359	24,942
Wisconsin	220	14,432	24,696	52,282	91,410	45,610
Wyoming 1/	41	2,789	2,794	5,757	11,340	6,697
American Samoa	0	0	0	0	0	0
Guam	5	1,013	1,220	1,957	4,190	3,741
North Mariana Island	0	0	0	0	0	0
Puerto Rico	113	37,020	48,588	83,610	169,218	111,491
Trust Territory	0	0	0	0	0	0
(excluding NM)	0	0	0	0	0	0
Virgin Islands	7	983	1,560	3,997	6,540	5,610
Indian Tribe Set Asi	0	0	0	0	0	0
Indian Tribes	0	0	0	0	0	0
Freely Associated States	0	0	0	0	0	0
DDO Army/AF/USMC/Navy	0	0	0	0	0	0
Undistributed	0	0	0	0	0	-797
TOTAL	9,038	1,364,018	1,741,583	2,813,504	5,919,105	\$2,920,242 3/

1/ Includes Indian Agencies.

2/ Number of clinics reported for FY 1993. Number of clinics for FY 1994 not available.

3/ Excludes \$4,711,023 for WIC Studies and evaluations, and \$3,249,822 for Farmers' Market Nutrition Program.

NOTE: These data are based in part on preliminary data submitted by State and local agencies and are subject to change as revised reports are received. Totals may not add due to rounding.

FOOD AND NUTRITION SERVICE

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

Commodity Supplemental Food Program:

For necessary expenses to carry out the commodity supplemental food program as authorized by section 4(a) of the Agriculture and Consumer Protection Act of 1973 (7 U.S.C. 612c (note)), including not less than \$8,000,000 for the projects in Detroit, New Orleans, and Des Moines, [\$104,500,000] \$94,500,000 to remain available through September 30, [1995] 1996:
Provided, That none of these funds shall be available to reimburse the Commodity Credit Corporation for commodities donated to the program.

This change makes the appropriation available through September 30, 1996.

COMMODITY SUPPLEMENTAL FOOD PROGRAM

Appropriations Act, 1994.....	\$104,500,000
Budget Estimate, 1995.....	<u>94,500,000</u>
Decrease in Appropriation.....	<u>-10,000,000</u>

SUMMARY OF INCREASES AND DECREASES
(On basis of appropriation)

<u>Item of Change</u>	<u>1994 Estimated</u>	<u>Program Changes</u>	<u>1995 Estimated</u>
Commodity Supplemental Food Program	<u>\$104,500,000</u>	<u>-\$10,000,000</u>	<u>\$94,500,000</u>

PROJECT STATEMENT
(On basis of appropriation)

<u>Project</u>	<u>1993 Actual</u>	<u>1994 Estimated</u>	<u>Increase or Decrease</u>	<u>1995 Estimated</u>
Commodity Supplemental	:	:	:	:
Food Program (CSFP)	:	:	:	:
Commodities.....	\$75,600,000:	\$83,600,000:	-8,000,000:	\$75,600,000
Administrative costs...	18,900,000:	20,900,000:	-2,000,000:	18,900,000
Total, Available or	:	:	:	:
Estimate.....	<u>94,500,000:</u>	<u>104,500,000:</u>	<u>-10,000,000:</u>	<u>94,500,000</u>

PROJECT STATEMENT
(On basis of available funds)

<u>Project</u>	<u>1993 Actual</u>	<u>1994 Estimated</u>	<u>Increase or Decrease</u>	<u>1995 Estimated</u>
Commodity Supplemental	:	:	:	:
Food Program (CSFP)	:	:	:	:
Commodities.....	\$63,321,768:	\$83,600,000:	-\$8,000,000:	\$75,600,000
Administrative costs...	19,012,529:	20,900,000:	-2,000,000:	18,900,000
Total Obligations	<u>82,334,297:</u>	<u>104,500,000:</u>	<u>-10,000,000:</u>	<u>94,500,000</u>
Recovery of prior year	:	:	:	:
obligations	-2,876,767:	—	—	—
Unobligated balances....	:	:	:	:
Available, start of	:	:	:	:
year...a/.....	—	-12,280,664:	—	—
Available, end of	:	:	:	:
year...a/.....	12,280,664:	—	—	—
Expiring...a/.....	2,761,806:	+12,280,664:	—	—
Total, Available or	:	:	:	:
Estimate.....	<u>94,500,000:</u>	<u>104,500,000:</u>	<u>-10,000,000:</u>	<u>94,500,000</u>

a/ Proposed for rescission.

EXPLANATION OF PROGRAM

Overview of Program Development. Instituted in November 1968 through Public Law 90-463, the Commodity Supplemental Food Program (CSFP) is now authorized by section 4(a) of the Agriculture and Consumer Protection Act of 1973, as amended. The elderly component of CSFP was initiated by the Agriculture and Food Act of 1981, P.L. 97-98, which provided for pilot projects for low-income elderly persons in Polk County, Iowa and in Detroit, Michigan. These projects began operations in September 1982 and a pilot project in New Orleans, Louisiana, began after authorization by P.L. 97-370, December 18, 1982. The Food Security Act of 1985, P.L. 99-198, provided that funds available beyond those needed to serve women, infants, and children could be used to serve elderly persons beyond those participating in the original pilot project sites. The program was reauthorized through Fiscal Year 1995 by the Food, Agriculture, Conservation and Trade Act of 1990 (FACT), P.L. 101-624. This law increased administrative funding from 15 percent to 20 percent of funds appropriated, discontinued administrative funding based on the value of donated commodities, and allowed establishment of elderly-only sites.

Eligibility and Benefits. This program provides foods purchased by USDA to infants and children up to age six and to pregnant, postpartum and breastfeeding women and senior citizens who have low incomes and are residing in approved project areas. The foods are provided by the Department of Agriculture for distribution through State agencies and are intended to supplement food acquired by recipients with their own money, the Food Stamp Program, or other resources. The authorized commodities are iron-fortified infant formula and cereal, adult cereals, canned juice, evaporated milk and/or nonfat dry milk, canned vegetables and/or fruits, canned meat, poultry or tuna, egg mix, dehydrated potatoes, rice or pasta, and peanut butter or dry beans. Elderly participants are eligible to receive all commodities except iron-fortified infant formula and infant cereal.

CSFP participants sometimes receive "bonus" commodities in addition to the basic food package. As required by P.L. 101-624, 9 million pounds of cheese will be provided as a bonus commodity in Fiscal Years 1994 and 1995, if available, through the Commodity Credit Corporation (CCC) inventory.

When an excess of appropriate commodities are held in CCC inventory, they may be donated by CCC without charge to the CSFP appropriation and used to fulfill part of the entitlement. Such donated commodities are referred to as "free foods." In both Fiscal Years 1994 and 1995, a total of 4 million pounds each year of nonfat dry milk will be donated to this program as required by P.L. 101-624 to the extent that the CCC inventory levels permit. Additionally, CSFP received approximately 17 million pounds of bonus orange juice. Since free foods are not charged against the CSFP appropriation, funds that are saved can be made available for participant service.

State/Federal Responsibilities. The CSFP is operated as a State/Federal partnership under agreements signed by State health care, agricultural or education agencies and the Food and Nutrition Service. The Federal government provides all commodities distributed to participants through the program. Under current law, States are given 20 percent of the Federal funds appropriated to cover administrative costs. Allowable costs include nutrition education, warehousing, food delivery, participant certification, and other costs associated with State and local administration of the program.

JUSTIFICATION OF INCREASES AND DECREASES

- (1) A decrease of \$10,000,000 in the appropriation for the Commodity Supplemental Food Program (\$104,500,000 appropriated in 1994).

Need for Change. The requested amount will return funding to the 1993 level and the 1995 target level of the 1994 budget request. This amount will support an estimated average caseload level of 367,000. Priority will continue to be given to serving women, infants, and children, consistent with the Administration's emphasis to fully fund nutrition services to this vulnerable target population. A portion of the caseload will be supported by available program inventories.

Nature of Change. A funding level of \$94,500,000 will be needed in Fiscal Year 1995.

	FY 1993 <u>Actual</u>	FY 1994 <u>Estimate</u>	FY 1995 <u>Estimate</u>	<u>Change</u>
Caseload/Participation (avg.)				
(in thousands): 1/				
Women, Infants, Children	229	257	257	—
CSFP/Elderly	141	174	110	-64
Program Level (\$ in millions):				
Distributed food costs 2/.....	\$73.9	\$80.5	\$76.4	-4.1
Inventory Change	-11.5	+2.4	-1.5	-3.9
Subtotal, Commodity Purchases.....	62.4	82.9	74.9	-8.0
State and local administrative costs	19.0	20.9	18.9	-2.0
Commodity Administrative Cost & PCIMS9	.7	.7	—
Total.....	\$82.3	\$104.5	\$94.5	-\$10.0
Average food cost per person per month:				
Women, Infants and Children:				
Entitlement	\$18.66	\$18.90	\$19.21	+\$0.31
FNS funded	(17.66)	(16.63)	(18.21)	(+1.58)
Free substitute (donated)...	(1.00)	(2.27)	(1.00)	(-1.27)
Bonus (donated)	3.62	3.68	3.74	+0.06
Average per person total commodities	\$22.28	\$22.58	\$22.95	+\$0.37

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	FY 1993 <u>Actual</u>	FY 1994 <u>Estimate</u>	FY 1995 <u>Estimate</u>	<u>Change</u>
Elderly:				
Entitlement	\$16.29	\$16.47	\$16.76	+\$0.29
FNS funded	(14.90)	(14.01)	(15.37)	(+1.36)
Free substitute(donated).....	(1.39)	(2.46)	(1.39)	(-1.07)
Bonus (donated)	4.49	4.56	4.63	+0.07
Average per person total commodities	\$20.78	\$21.03	\$21.39	+\$0.36

1/ Higher participation in Fiscal Year 1994 is supported, in part, due to a one-time donation of \$4.7 million of orange juice. Further caseload increases may be made if funds carried forward from Fiscal Year 1993 are not rescinded.

2/ Includes commodities distributed from inventory.

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COMMODITY SUPPLEMENTAL FOOD PROGRAM (CSFP)

STATUS OF PROGRAM

Commodity Supplemental Food Program (CSFP)

The Commodity Supplemental Food Program provides federally purchased commodities and administrative funds to States which distribute the commodities to low-income pregnant, postpartum, and breastfeeding women, infants, and children up to age 6 and persons 60 years of age and older residing in the service areas. The quantity and varieties of commodities are determined by the Secretary of Agriculture.

Program Caseload

In Fiscal Year 1993 there were 20 State agencies operating the program. Sixteen of the State agencies also serve elderly participants. In Fiscal Year 1993, available funds supported a caseload allocation of 236,148 women, infants and children and 152,489 elderly. The average monthly participation in Fiscal Year 1993 was about 229,181 women, infants and children, and about 141,634 elderly. In Fiscal Year 1994, funds will support a caseload allocation of 257,088 women, infants and children and 173,788 elderly.

"Participation" refers to the actual number of participants served by a State agency, while "caseload" refers to the number of slots allocated. The base caseload for a State agency is determined according to the highest of the previous fiscal year's average participation, September participation, or fourth quarter average participation, not to exceed its previous caseload authorization level. Expansion caseload is then apportioned according to funds available, with priority going to women, infants and children slots. Ninety days after caseload is announced, a State agency may request FNS approval to convert unused women, infants, and children slots to elderly slots.

Purchases for the Commodity Supplemental Food Program (CSFP) and the Food Distribution Program on Indian Reservations (FDPIR) were reduced in Fiscal Year 1993. Some direct shipments were not purchased, but were filled from storage to reduce excessive inventories. The excessive inventories were caused by inventory identification problems due to conversion data from PCI to PCIMS, declining participation in the programs, and the additional inventory of reconditioned product from the Americold Fire. Excess Fiscal Year 1993 funds may be carried over for use in Fiscal Year 1994 after the reconciliation is completed.

Food Package

Six USDA purchased food packages are provided as benefits according to the following age or categories of participants: (1) infants - birth through 3 months; (2) infants - 4 through 12 months; (3) children - 1 to 6 years; (4) pregnant and breastfeeding women; (5) non-breastfeeding postpartum women; and (6) the elderly. The food packages reflect the health and nutritional requirements of participant categories.

CSFP participants receive monthly food packages which include: juice, hot or cold cereal, nonfat dry milk, evaporated milk, egg mix, dry beans or peanut butter, canned fruits or vegetables, canned meat, tuna or poultry, and dehydrated potatoes, rice or pasta. Infants receive formula and rice cereal. In Fiscal Year 1993, participants also received, as bonus foods, cheese, butter, honey, cornmeal, and nonfat dry milk. The Commodity Credit Corporation provided 9,000,000 pounds of cheese and 4,000,000 pounds of nonfat dry milk as required by P.L. 101-624, the FACT Act.

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COMMODITY SUPPLEMENTAL FOOD PROGRAM
Quantity and Value of Commodities

By Commodity, Fiscal Year 1993

ENTITLEMENT COMMODITIES	Pounds	Dollars
SECTION 6/32 TYPE:		
APPLE JUICE, CANNED	17,710,540	\$4,633,465
APPLESAUCE, CANNED	1,366,728	481,721
BEANS, DRY	2,165,736	640,944
BEANS, GREEN, CANNED	1,952,404	543,824
BEEF, CANNED W/NJ	1,221,900	1,822,021
BEEF, MEATBALL STEW	548,986	414,401
CARROTS	1,416,144	430,829
CHICKEN, CANNED BONELESS	2,464,398	4,797,958
CORN, CANNED, CREAM STYLE	584,160	194,783
CORN, CANNED, WHOLE KERNEL	898,800	303,939
EGG MIX	2,674,854	4,791,132
FRUIT COCKTAIL, CANNED	1,759,344	1,086,171
GRAPE JUICE, CANNED	6,585,172	2,222,043
GRAPEFRUIT JUICE, CANNED	2,410,032	583,263
ORANGE JUICE, CANNED	18,717,953	4,590,446
PEACHES, CLING CANNED	2,793,456	1,696,276
PEARS, CANNED	1,272,984	504,036
PEAS, GREEN CANNED	1,535,784	559,589
PINEAPPLE JUICE, CANNED	5,556,575	1,659,237
PINEAPPLE, CANNED	992,370	530,299
PLUMS, CANNED, PURPLE	313,608	122,343
PORK, CANNED, W-NJ	1,453,648	2,010,359
POTATOES, DEHYDRATED	1,223,772	647,370
POTATOES, WHOLE	477,336	141,516
PUMPKIN	255,576	88,530
SPINACH, CANNED	242,304	82,793
SWEET POTATOES, SYRUP	835,272	397,432
TOMATO JUICE, CANNED	1,108,740	233,009
TOMATOES, CANNED	6,616,328	199,304
TUNA, CHUNK	1,882,401	2,444,895
Total Section 6/32 Type	83,035,305	\$38,944,128
SECTION 416-TYPE:		
CEREAL, DRY CORN	1,525,223	1,678,277
CEREAL, DRY RICE	1,731,394	1,871,009
CEREAL, INFANT RICE	369,312	533,742
CEREAL, DRY OATS	709,066	1,000,913
CEREAL, WHEAT	266,112	364,646
FARINA	2,769,690	1,048,487
FORMULA, INFANT	6,147,389	4,709,992
MACARONI	1,203,960	346,412
MILK, EVAPORATED	20,008,600	9,099,261
MILK, WFD	7,157,304	8,395,296
OATS, ROLLED	745,236	145,929
PEANUT BUTTER	3,104,688	2,494,779
RICE, MILLED	2,728,368	534,032
SPAGHETTI	517,752	160,663
Total Section 416-Type	48,984,094	\$32,383,438
Anticipated Adjustment		-7,136,798
AMS/ASCS/PCIMS Admin. Expenses		869,000
Total Commodity Entitlement	132,019,399	\$63,321,768
BONUS COMMODITIES		
SECTION 6/32 TYPE:		
ORANGE JUICE	37,800	10,056
Total Section 6/32-Type	37,800	10,056
SECTION 416-TYPE:		
BUTTER	2,879,676	\$2,706,389
CHEESE PROCESS	8,995,080	12,057,897
CORNMEAL	8,330,350	1,060,793
HONEY	1,578,744	466,382
WFD MILK	3,937,176	4,625,757
Total Section 416 Type	25,721,026	\$20,917,218
Total Bonus Commodities	25,758,826	\$20,927,274
GRAND TOTAL (Entitlement & Bonus)	157,778,225	\$84,249,042

SOURCE: Preliminary food orders for fiscal year 1993.

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COMMODITY SUPPLEMENTAL FOOD PROGRAM
PROJECTS, PARTICIPATION AND FOOD COST
FISCAL YEAR 1993

STATE OR TERRITORY	AVERAGE MONTHLY PARTICIPATION (FNS-153)						FOOD VALUE IN DOLLARS	1/
	PROJECTS	WOMEN	INFANTS	CHILDREN	ELDERLY	TOTAL		
Arizona	11	3,139	0	15,259	6,877	25,275	\$4,561,901	
California	2	1,239	953	9,435	3,046	14,673	2,779,659	
Colorado	7	3,491	3,341	11,021	6,122	23,975	5,088,749	
District of Columbia	1	710	609	4,463	9,486	15,268	2,795,580	
Illinois	1	2,510	2,175	10,937	5,727	21,349	4,347,300	
Iowa	1	294	136	1,323	3,976	5,729	1,004,841	
Kansas	3	821	0	2,483	1,173	4,477	913,517	
Kentucky	1	356	245	2,189	4,017	6,807	1,366,090	
Louisiana	1	4,292	3,268	19,694	31,115	58,369	11,837,026	
Michigan	8	8,967	6,533	42,889	38,913	97,302	19,437,057	
Red Lake, Minn.	1	97	89	404	0	590	123,037	
Minnesota	2	1,216	417	5,683	2,406	9,722	2,020,145	
Nebraska	7	690	181	3,569	10,475	14,915	2,783,431	
New Hampshire	4	831	0	1,449	1,408	3,688	706,210	
New Mexico	4	2,257	148	13,931	2,391	18,727	3,806,570	
New York	2	3,680	3,162	13,654	0	20,496	4,681,764	
North Carolina	1	46	36	336	1,558	1,976	371,019	
Oregon	1	49	41	1,104	0	1,194	246,929	
Ogala Sioux, S.D.	1	52	40	598	0	690	161,389	
Tennessee	4	1,744	995	9,910	12,944	25,593	4,864,011	
AMS/ASCS/PCIMS Ad. Exp.	0	0	0	0	0	0	869,000	
Anticipated Adjustment	0	0	0	0	0	0	-11,443,457	
TOTAL	63	36,481	22,369	170,331	141,634	370,815	\$63,321,768	

1/ Total value of entitlement foods.

NOTE: These data are based in part on preliminary data submitted by State and local agencies and are subject to change as revised reports are received.

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FOOD AND NUTRITION SERVICE

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

Food Stamp Program:

1 For necessary expenses to carry out the Food Stamp Act (7 U.S.C.2011-2029),
 2 [\$28,136,655,000] \$27,687,710,000: Provided, That funds provided herein
 3 shall remain available through September 30, [1994] 1995, in accordance with
 4 section 18(a) of the Food Stamp Act: Provided further, That \$2,500,000,000
 of the foregoing amount shall be placed in reserve for use only in such
 amounts and at such times as may become necessary to carry out program
 operations: Provided further, That funds provided herein shall be expended
 in accordance with section 16 of the Food Stamp Act: Provided further, That
 this appropriation shall be subject to any work registration or work fare
 requirements as may be required by law. [: Provided further, That
 \$345,000,000 of the funds provided herein shall be available after the
 Secretary has employed the regulatory and administrative methods available
 to him under the law to curtail fraud, waste, and abuse in the program:
 Provided further, that \$1,091,000,000 of the foregoing amount shall be
 available for Nutrition Assistance for Puerto Rico as authorized by 7 U.S.C.
 2028, of which \$12,472,000 shall be transferred to the Animal and Plant
 Health Inspection Service for the Cattle Tick Eradication Project.] For
making after May 31 of the current fiscal year, benefit payments to
individuals under the Food Stamp Act for unanticipated costs incurred for
the current fiscal year, such sums as may be necessary. For necessary
expenses to carry out the Food Stamp Act (7 U.S.C.2011-2029), for the first
quarter of fiscal year 1996, \$7,200,000,000 to remain available through
September 30, 1996.

The first change makes the appropriation available through September 30, 1995.

The second change deletes unnecessary language.

The third change deletes the provision applicable to Nutrition Assistance to Puerto Rico. Appropriations for this activity are requested in a separate account.

The fourth change provides indefinite spending authority after May 31, 1994 to ensure that adequate funds are available for payment of program benefits, and makes advance appropriations for a portion of Fiscal Year 1996 budget authority to ensure availability of funds at the beginning of the fiscal year.

FOOD STAMP PROGRAM - CURRENT LAW

Appropriations Act, 1994.....	\$27,045,655,000
Budget Estimate, 1995.....	<u>27,687,710,000</u>
Increase in the Appropriation.....	<u>+642,055,000</u>

SUMMARY OF INCREASES AND DECREASES-CURRENT LAW
(On basis of appropriation)

<u>Item of Change</u>	<u>1994 Estimated</u>	<u>Pay Cost</u>	<u>Program Changes</u>	<u>1995 Estimated</u>
<u>Benefits:</u>				
Total, Benefit				
Costs.....	\$22,826,031,000	--	+\$640,267,000	\$23,466,298,000
Reserve Expiring....	2,500,000,000	--	--	2,500,000,000
<u>Administrative costs:</u>				
Payments to States..	1,614,079,000	--	+17,146,000	1,631,225,000
Other program costs..	<u>106,545,000</u>	<u>48,000</u>	<u>+5,194,000</u>	<u>111,787,000</u>
Total Admin. costs..	1,720,624,000	48,000	+22,340,000	1,743,012,000
Liabilities and collections.....	<u>-1,000,000</u>	<u>--</u>	<u>-20,600,000</u>	<u>-21,600,000</u>
Total, Appropriation	27,045,655,000	48,000	+642,007,000	27,687,710,000

PROJECT STATEMENT
(On basis of appropriation)

	1993		1994		Increase	1995	
	Actual		Estimated		or	Estimated	
Project	Amount	SYs	Amount	SYs	Decrease	Amount	SYs
Benefits:							
Correct benefits	\$21,013,710,000:		\$21,045,601,000:		+\$63,258,000:	\$21,682,859,000:	
Err. benefits.....	<u>1,827,279,000:</u>		<u>1,780,430,000:</u>		<u>+3,009,000:</u>	<u>1,783,439,000:</u>	
Total, Ben. Costs...	22,840,989,000:		22,826,031,000:		+\$640,267,000:	23,466,298,000:	
Administrative					(2):		
Costs.....	1,463,456,000:		1,451,336,000:		+14,865,000:	1,466,201,000:	
					(3):		
Employ. & Training:	166,770,000:		162,743,000:		+2,281,000:	165,024,000:	
Other Program Costs:							
Food Stamp prod.....					(a):		
and redemption.....	70,954,000:		73,862,000:		+2,441,000:	76,303,000:	
Computer support					(b):		
Systems..g/.....	2,370,000:		1,496,000:		+460,000:	1,956,000:	
Certification of SSI:							
recipients for food:					(c):		
stamps.....	4,000,000:		4,080,000:		+69,000:	4,149,000:	
Retailer redemption:					(d):		
monitoring system:	2,000,000:		2,040,000:		+354,000:	2,394,000:	
Recipient and coop-					(e):		
erative services..g/:	1,158,000:		1,101,000:		+610,000:	1,711,000:	
Research, evaluation:					(f):		
& demo projects..g/:	9,600,000:		10,886,000:		+794,000:	11,680,000:	
					(g):		
Retail Integrity and:					(1):		
Trafficking..a/.....	1,950,000:12		1,959,000:12		+28,000:	1,987,000:12	
Electronic Benefit:					(h):		
Transfer..g/.....	610,000:13		10,607,000:13		-0-:	10,607,000:18	
Nutrition, Education:					(i):		
Initiative..g/.....	500,000:		514,000:		-514,000:	-0-:	
					(j):		
Error Reduction..g/:	--		--		+1,000,000:	1,000,000: 5	
Subtotal, Other					(4):		
Program Costs.....	<u>93,142,000:25</u>		<u>106,545,000:25</u>		<u>+5,242,000:</u>	<u>111,787,000:35</u>	
Total, Administra-							
tive costs.....	<u>1,723,368,000:25</u>		<u>1,720,624,000:25</u>		<u>+22,398,000:</u>	<u>1,743,012,000:35</u>	
Benefit Reserve	2,500,000,000:		2,500,000,000:		--	2,500,000,000:	
Liabilities							
and Collections.....			-1,000,000:		-20,600,000:	-21,600,000:	
Total, Available or					(5):		
Estimate.....	<u>27,064,357,000:25</u>		<u>27,045,655,000:25</u>		<u>+642,055,000:</u>	<u>27,687,710,000:35</u>	
Total, Budget							
Request.....	<u>27,064,357,000:25</u>		<u>27,045,655,000:25</u>		<u>+642,055,000:</u>	<u>27,687,710,000:35</u>	

a/ Fiscal Year 1995 amounts include a request of \$13,253,000 in discretionary additions to the mandatory baseline.

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PROJECT STATEMENT
(On basis of available funds)

	1993		1994		Increase	1995	
	Actual		Estimated		or	Estimated	
Project	Amount	SYS:	Amount	SYS:	Decrease	Amount	SYS:
Benefits:					(1):		
Correct benefits...	\$20,249,637,209:		\$20,763,546,000:		+\$19,313,000:	\$21,682,859,000:	
Erroneous benefits:	1,760,838,018:		1,756,569,000:		+26,870,000:	1,783,439,000:	
Total, Benefit costs:	22,010,475,227:		22,520,115,000:		+\$946,183,000:	23,466,298,000:	
Administrative					(2):		
Costs.....	1,461,151,068:		1,451,336,000:		+14,865,000:	1,466,201,000:	
Employ. & Training..:	157,669,879:		162,743,000:		+2,281,000:	165,024,000:	
Other Program Costs:							
Food Stamp product.					(a):		
and redemption....:	46,487,520:		73,862,000:		+2,441,000:	76,303,000:	
Computer support					(b):		
Systems..a/.....:	2,368,414:		1,496,000:		+460,000:	1,956,000:	
Certification of SSI:					(c):		
recipients for food:	4,000,000:		4,080,000:		+69,000:	4,149,000:	
Retailer redemption:					(d):		
& monitoring system:	2,000,000:		2,040,000:		354,000:	2,394,000:	
Recipient and coop-					(e):		
erative services..a/:	880,328:		1,101,000:		610,000:	1,711,000:	
Research, evaluation:					(f):		
& demo projects..a/:	9,579,420:		10,886,000:		+794,000:	11,680,000:	
Retail Integrity and:					(g):		
Trafficking....a/..:	1,926,148:12		1,959,000:12		+28,000:	1,987,000:12	
Electronic Benefit					(h):		
Transfer..a/.....:	608,721:13		10,607,000:13		-0:	10,607,000:18	
Nutrition, Education:					(i):		
Initiative..a/.....:	510,373:		514,000:		-514,000:	-0-	
Error Reduction..a/:	--		--		+1,000,000:	1,000,000: 5	
Subtotal, Other					(4):		
Program Costs.....:	68,360,924:25		106,545,000:25		+5,242,000:	111,787,000:35	
Total, Administra-							
tive costs.....:	1,687,181,871:25		1,720,624,000:25		+22,388,000:	1,743,012,000:35	
Total, Obligations..:	23,697,657,098:		24,240,739,000:		+\$968,571,000:	25,209,310,000:	
Unobligated balances:							
Available, start							
of year.....:	-308,000,000:		--		--	--	
Available, end of							
year.....:	--		--		--	--	
Unob. Bal. Expir....:	3,674,699,902:		2,805,916,000:		-305,916,000:	2,500,000,000:	
Subtotal, Available							
or Estimate.....:	27,064,357,000:25		27,046,655,000:25		+662,655,000:	27,709,310,000:35	
Liabilities and					(5):		
Collections.....:			-1,000,000:		-20,600,000:	-21,600,000:	
Total, Available or							
Estimate.....:	27,064,357,000:25		27,045,655,000:25		+642,055,000:	27,687,710,000:35	
Total, Budget							
Request.....:	27,064,357,000:25		27,045,655,000:25		+642,055,000:	27,687,710,000:35	

Fiscal Year 1995 amounts include a request of \$13,253,000 in discretionary additions to the mandatory baseline.

EXPLANATION OF PROGRAM

Overview of Program Development. The Food Stamp Program, which is authorized through September 30, 1995 by the Food, Agriculture, Conservation and Trade (FACT) Act of 1990, P.L. 101-624, helps individuals and families with low incomes obtain a more nutritious diet. The program was initiated on a pilot basis in 1961 and established as a permanent program in 1964. The Food Stamp Program enables low-income households to obtain better diets by supplementing the funds they have to spend on food with food stamps which may be used for purchasing food items at authorized food stores. The Food Stamp Program evolved from the Commodity Distribution to Needy Families Program established in 1936. Commodities purchased for farm assistance purposes were made available for distribution to needy individuals through various Federal, State, and local welfare organizations. In 1961, the basic emphasis of commodity donations changed significantly when an Executive Order expanded the program's objectives from removing surpluses to also encompass raising the quantity and improving the quality of foods distributed. Beginning in that year a food stamp pilot project was undertaken in a number of States.

The Food Stamp Act of 1964 authorized a permanent Food Stamp Program which would gradually supplant commodity distribution. The program was implemented in most counties by 1969, although it was not until Fiscal Year 1975 that the Food Stamp Program expanded to all counties nationally. The Food Stamp Program is currently in operation in all 50 States, the District of Columbia, the Virgin Islands, and Guam. Puerto Rico and the Commonwealth of the Northern Mariana Islands operate block grant programs in lieu of the regular Food Stamp Program.

Eligibility and Benefits. Eligible participants are entitled to food stamp allotments based on their household size and net income after certain deductions. Food stamps increase the food purchasing power of eligible households and thus enable them to attain a better diet than would have been possible without the assistance.

Benefit Costs. The cost of food stamps is paid by the Federal government and is called "benefit" costs. Benefits are issued to program recipients as follows:

1. Regular Issuance -- Food coupons/stamps are the most common form of benefit and are issued on a monthly basis to eligible recipients.
2. Alternative Issuance -- Electronic Benefit Transfer (EBT) is the major alternative method of providing program participants with the value of the coupons used to make food purchases. EBT projects are currently operating statewide in Maryland and in parts of Pennsylvania, Minnesota, Ohio, New Mexico, and Iowa and are planned in other States. Under this system each recipient household is issued a plastic benefit card with a magnetic stripe or a computer chip to make food purchases; no cash or food coupons are involved. At the store, the recipient presents his/her card and enters a unique personal identification number into a terminal that immediately debits the household's account for the amount of purchase at a centralized computer or on the computer chip. The grocer's account at a designated bank is credited for the same amount by a financial institution. Federal funds are shifted from the Federal Reserve to the financial institution to complete the settlement process. In Fiscal Year 1992, regulations were promulgated as required by statute to make EBT available as an operational alternative nationwide.
3. Cash-out and some welfare reform projects enable participants to use cash in lieu of coupons to make their food purchases. Cash-out projects are currently operating in California, Minnesota and Vermont. One county in the States of California, Ohio, and Virginia, four counties in Oregon, and 2 counties in Wisconsin will begin operating cash-out projects in 1994. Allotments are issued to recipient households in the form of a check. Welfare reform projects are currently underway in Alabama and New York. A project in Utah was approved in Fiscal Year 1993 to run through February 1998. The Food Stamp Program aspect of the Washington Family Independence Project ended June 30, 1993.

Generally, the projects consolidate AFDC, General Assistance for families, and food stamps to form a single unified program with one set of rules and with benefits issued in the form of one cash grant to families.

It is estimated that approximately \$700-800 million in benefits will be issued through these alternate methods in Fiscal Year 1994.

4. The Thrifty Food Plan is a model plan for achieving a nutritionally adequate diet. As required by law, the food stamp allotments for the various household sizes are revised October 1 of each year to reflect changes in the

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cost of the Thrifty Food Plan as of the prior June. The maximum benefit for a family of four is 103 percent of the value of the estimated plan.

5. A small modified block grant (\$3.7 million) is provided to the Commonwealth of the Northern Mariana Islands in lieu of the regular Food Stamp Program.

State Administration. All direct and indirect administrative costs incurred for certification of households, issuance of food stamps, quality control and fair hearing efforts are shared by the Federal government and the States on a 50-50 basis. Under current law, enhanced Federal funding is available for one ADP system development per State. Costs incurred for proposals approved before November 28, 1990 will be matched at 75 percent; costs incurred for proposals approved after that date will be supported at 63 percent until April 1, 1994 at which time enhanced funding will no longer be available. State agencies can also receive at least 75 percent funding for fraud prevention related activities until April 1, 1994 at which time enhanced funding will no longer be available. For States with low error rates, the normal 50 percent Federal share of State administrative costs can be increased up to a maximum of 60 percent, depending on the extent to which the State's error rate falls below 6 percent. In order to receive this incentive funding, States must also meet a standard set by the Secretary for the rate of improper denials or terminations. State agencies are held liable when their rate of overissuances and payments to ineligible households plus their rate for underissuances exceeds the national performance measure for that year. Liabilities are based on the level of State issuance and the extent to which the State's error rate exceeds the tolerance level. Those States closer to the National Performance Measure pay proportionately less than those further away from the National Performance Measure which is the national average error rate.

Employment and Training Program (E&T). States are required to conduct an employment and training program for the purpose of assisting members of households participating in the Food Stamp Program in gaining skills, training or experience that will increase their ability to obtain regular employment. In Fiscal Year 1994, the Department will provide States 100 percent Federal grants totaling \$75 million, of which \$15 million will be based on State agency performance in placing participants into E&T programs. Additional funds will be spent by State agencies and matched by the Federal government to administer E&T programs.

Other Program Costs. In addition to State administrative and employment and training expenses, other program costs borne by the Federal government include:

- (1) the printing and transporting of food stamps to State agencies; processing and destruction of redeemed food stamps by Federal Reserve Banks; and settlement.
- (2) the computer support systems;
- (3) the certification of SSI/Social Security recipients for participation in the Food Stamp Program by the district offices of the Social Security Administration;
- (4) the redemption and monitoring system;
- (5) recipient and cooperative services including funds for printing other than stamps, State Exchange and collection of Quality Control liabilities and other claims;
- (6) research, evaluation and demonstration projects authorized under Section 17 of the Food Stamp Act of 1977;
- (7) retailer integrity;
- (8) electronic benefit transfer;
- (9) tax refund offset; and
- (10) error reduction.

State/Federal Responsibilities. The Food Stamp Program is a Federal-State partnership in which the States administer the program at the service delivery level. Households apply for food stamps at their local State welfare offices. State workers use uniform nationwide rules promulgated by the Food and Nutrition Service to determine and certify which households are eligible, to calculate the size of each household's allotment, and to monitor and recertify recipient eligibility. Food stamps are typically dispensed on a monthly basis through local banks or the mail.

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Each State must have an Employment and Training (E&T) program to help able-bodied individuals in food stamp households gain skills and experience that will help them obtain regular employment.

The Quality Control System encourages payment accuracy by establishing fiscal incentives based on State performance in benefit determinations. State agencies with high error rates are assessed liabilities, while enhanced administrative funding is provided to States with low error rates.

FNS funds 100 percent of the cost of food stamps redeemed. FNS also funds 50 percent of State administrative costs for the program. FNS is responsible for authorizing and monitoring stores participating in the program. Approximately 208,000 stores are authorized to redeem food stamps.

After recipients use their food stamps to purchase food at stores, the stores redeem the food stamps at banks. The banks, in turn, redeem the food stamps at their regional Federal Reserve Bank, and the Federal Reserve Bank seeks reimbursement from the FNS appropriation directly from the U.S. Treasury. FNS also monitors the redemption process on an ongoing basis.

JUSTIFICATION OF INCREASES AND DECREASES

- (1) An increase of \$640,267,000 in the appropriation for Benefit Costs, including the effects of the Mickey Leland Childhood Hunger Relief Act (\$22,826,031,000 budgeted in 1994). The increase consists of:

- (a) An increase of \$637,258,000 for properly issued benefits (\$21,045,601,000 available in 1994)

Need for Change. In Fiscal Year 1995, the anticipated increase in the value of the Thrifty Food Plan (TFP) as well as maintaining the maximum benefit level at 103 percent of the TFP will result in an increase in benefits for all households. Program participation is expected to decrease from 27.4 million per month in Fiscal Year 1994 to 27.3 million per month in Fiscal Year 1995. In addition, the Budget request includes a reserve of \$2.5 billion to be used if unforeseen economic or other circumstances cause an increase in required program payments.

Nature of Change. A comparison of key program workload and cost indicators for Fiscal Years 1993 through 1995 is presented below:

	FY 1993 <u>Actual</u>	FY 1994 <u>Estimate</u>	FY 1995 <u>Estimate</u>
Average participation (000)	26,983	27,394	27,314
Average unemployment rate (percent)	7.00	6.60	6.20
Thrifty Food Plan	\$355.50	\$364.90	\$374.90
Maximum Allotment	\$370	\$375	\$386
Average benefit per person per month	\$67.98	\$68.51	\$71.60

- (b) An increase of \$3,009,000 for erroneous benefits (\$1,780,430,000 budgeted in Fiscal Year 1994).

Need for Change. The overpayment error rate is projected to decline from 7.8 percent in Fiscal Year 1994 to 7.6 percent in Fiscal Year 1995. The dollar value for overall benefit costs is expected to increase, the amount of erroneously issued benefits is expected to increase slightly.

Nature of Change. A comparison of overpayment error rates and erroneous benefits follows:

	FY 1993 <u>Actual</u>	FY 1994 <u>Estimate</u>	FY 1995 <u>Estimate</u>
Amount of erroneous benefits (\$ millions)	\$1,761	\$1,756	\$1,783
Overpayment Error rate	0.080	0.078	0.076

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- (2) An increase of \$14,865,000 in the appropriation for State administrative costs, including the effects of the Mickey Leland Childhood Hunger Relief Act (\$1,451,336,000 available in 1994).

Need for Change. Based on the most recent economic projections, moderate rates of inflation between 1994 and 1995 are expected to increase the cost of providing food stamp benefits.

Nature of Change. This increase reflects the application of a projected rate of inflation of 2.6 percent to the Fiscal Year 1994 base level for costs shared by State and local agencies and the Federal Government.

- (3) An increase of \$2,281,000 in the appropriation for the Employment and Training Program (\$162,743,000 available in 1994).

Need for Change. This increase is necessary to provide matching funds for participant reimbursements and State administrative costs to carry out the Employment and Training Program.

Nature of Change. Public Law 99-195 mandates the Secretary to allocate funds among the States to carry out the Employment and Training Program. This level of funding will enable the Department to provide States \$75 million authorized for 100 percent federally-funded grants, additional matching funds for participant reimbursements and matching funds for additional State administrative costs to assist them in providing employment and training services.

- (4) A net increase of \$5,242,000 in the appropriation for Other Program Costs, including the effects of the Omnibus Reconciliation Act of 1993 (\$106,545,000 available in Fiscal Year 1994).

Need for Change. Increases in other program costs are primarily attributed to increases associated with higher program benefit payments and the rates of inflation projected between 1994 and 1995, the need for developing protocol to support large scale Electronic Benefit Transfer (EBT) systems, and program integrity.

Nature of Change.

- (a) Food Stamp Production and Redemption:

An increase of \$1,239,000 is required in the appropriation for printing of stamps (\$45,514,000 available in Fiscal Year 1994). An increase of \$89,000 is needed in the appropriation for shipping of stamps (\$5,263,000 budgeted in Fiscal Year 1994). An increase of \$1,113,000 is necessary in the appropriation for processing redeemed stamps with the Federal Reserve (\$23,085,000 budgeted in Fiscal Year 1994).

- (b) An increase of \$460,000 for the cost of computer support systems (\$1,496,000 budgeted in Fiscal Year 1994). The projected need for Fiscal Year 1995 includes funding for the Integrated Quality Control Project, the Disqualified Recipient System, and other program systems.
- (c) An increase of \$69,000 in the appropriation for the cost of certification of Supplemental Security Income recipients for food stamps (\$4,080,000 budgeted in Fiscal Year 1994).
- (d) An increase of \$354,000 in the appropriation for the cost of the retailer redemption and monitoring system (\$2,040,000 budgeted in Fiscal Year 1994). These funds are used to cover the printing and distribution cost of the redemption certificates used by retail stores in order to redeem their food stamps through the banking system. The \$354,000 increase in Fiscal Year 1995 is due to Store Tracking and Redemption Subsystem (STARS) enhancements as well as small incremental changes in software and maintenance fees.
- (e) An increase of \$610,000 in the appropriation for recipient and cooperative services (\$1,101,000 budgeted in Fiscal Year 1994). The \$1,711,000 projected need for Fiscal Year 1995 includes funding for printing other than stamps, the State Exchange Project and Food Stamp Program litigation costs and collection of claims.

- (f) An increase of \$794,000 in the appropriation for research, evaluation and demonstration projects (\$10,886,000 budgeted in Fiscal Year 1994). These funds support FNS' research agenda in several areas including welfare reform, coordination and simplification, and evaluation of program effectiveness and responsiveness. Up to \$2 million of these funds will be used to test improved food stamp delivery to rural, elderly and working people. Up to \$2.75 million of these funds will be used to test better integration of nutrition in the Food Stamp Program.
- (g) An increase of \$28,000 in the appropriation for retailer integrity (\$1,959,000 budgeted in Fiscal Year 1994) which includes \$19,200 for the Fiscal Year 1995 pay raise. This increase would support staff years and associated costs for retailer compliance and the retailer data base update. Retailer Integrity resources are used for:
 - o 12 investigator staff and related costs to concentrate on retailer food stamp trafficking;
 - o continued update of retailer data in the FNS automated database to assist in the identification and investigation of retailer trafficking.
- (h) The funding level for Electronic Benefit Transfer implementation and oversight is \$10,607,000 (\$10,607,000 budgeted in Fiscal Year 1994). Electronic Benefit Transfer resources include \$28,800 for the Fiscal Year 1995 pay raise and are used for:
 - o 18 staff years and related costs to concentrate on State implementation and operation of food stamp EBT;
 - o continued food stamp settlement service and reconciliation development, EBT system design, and remaining FNS food stamp systems modifications.
- (i) A decrease of \$514,000 in the appropriation for the Nutrition Education Initiative (\$514,000 budgeted in Fiscal Year 1994) since related efforts are planned under the area of research, evaluation, and demonstration projects.
- (j) An increase of \$1,000,000 in the appropriation for error reduction. The increase will provide for 5 staff years and enable increased Federal presence in working with the States to substantially improve their management oversight and administration of the Food Stamp Program in a manner which will reduce error rates.
- (5) An increase of \$20,600,000 for collections (\$1,000,000 budgeted in Fiscal Year 1994).

Need for Change. This estimate reflects an increase in collections, primarily through the Federal Tax Refund Offset Program, from States.

Nature of Change. The Fiscal Year 1995 estimate assumes that there will be a savings of \$21.6 million.

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FOOD STAMP PROGRAM

STATUS OF PROGRAM

The Food Stamp Program (FSP) supplements the food purchasing power of low-income households by issuing coupons redeemable for food at authorized retail stores. This program helps ensure that low income recipients have access to a nutritious diet and can follow the Dietary Guidelines for Americans. In addition to benefit costs, the Food Stamp appropriation provides for State administrative costs, and other program costs such as printing and distribution of food stamps and funds for grants to States for Employment and Training Program activities.

Fiscal Year 1993 saw the continuation of major efforts to improve the management of the Food Stamp Program. Attention remained focused on reducing Federal costs through improving program management and decreasing the instances of error, fraud, and abuse in the program while continuing to respond to the needs of low-income persons, in terms of both benefits and service. These program management improvements were the product of numerous administrative actions taken by the Food and Nutrition Service (FNS). Increased emphasis was also placed on Electronic Benefit Transfer (EBT), Nutrition Education, and efforts to conform program requirements to those of programs with similar participants. An important FNS initiative for Fiscal Year 1993 was proposing major legislation to significantly increase food stamp benefits, simplify and improve program administration, and help assure the integrity of the Food Stamp Program. The Administration's proposals were essentially retained in P.L. 103-66, the Mickey Leland Childhood Hunger Relief Act. Finally, significant activity resulted from FNS' operation of emergency disaster Food Stamp programs in three disaster-affected areas.

Program Participation

Participation during Fiscal Year 1993 averaged 27.0 million persons per month. Total benefit costs for Fiscal Year 1993 were \$22.0 billion for an average monthly benefit of \$67.98 per person. In Fiscal Year 1992, monthly participation averaged 25.4 million persons and monthly benefits averaged \$68.57 per person. Monthly unemployment averaged 7.3 percent in Fiscal Year 1992 and 7.0 percent in Fiscal Year 1993.

Food Stamp participation data for Fiscal Year 1993 indicates that the rate increase in program activity slowed significantly compared to the prior year. Average monthly participation grew by 1.6 million persons, 6.3 percent above Fiscal Year 1992. Average participation has risen by 8.2 million persons or 43.6 percent, in comparison to Fiscal Year 1989.

Fiscal Year 1993 growth represents the continuation of participation trends that began to emerge in the program early in the third quarter of Fiscal Year 1989. Our research attributes the start of this trend to a variety of reasons, and no single explanation predominates. The most important factors were the expansion of the Medicaid Program, the slackening of economic growth, and legislative and other changes intended to improve access to the program.

Characteristics of Food Stamp Households

The Food Stamp Program serves the nation's most needy households. The following information is derived from the Summer 1992 Characteristics of Food Stamp Households Report:

- The average household size is 2.5 persons.
- The average gross monthly income per food stamp household is \$481 (the annual equivalent of \$5,772); the average net income is \$258 a month -- \$3,096 a year.
- 10 percent of households have zero gross income and 20 percent have zero net income.
- 38 percent of all households have gross incomes of less than \$400 per month (the annual equivalent of \$4,800).
- 76 percent own no countable assets, and an additional 18 percent own countable assets valued at \$500 or less.
- Average countable assets per household were \$80, but for households with elderly members the average was \$198.
- Slightly over half (51.7 percent) of food stamp recipients are children, while 6.6 percent are elderly.

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- Food stamp recipients who are able to work are doing so or are meeting the program's work requirements in other ways.
- 7 percent of all heads of households are employed full-time.
- 20 percent of households have earned income.
- 32 percent of non-elderly adult participants are registered for work through the Food Stamp Program or are subject to the work requirements of the Aid to Families with Dependent Children program.

Significant Regulations and Notices Issued in Fiscal Year 1993

Food Stamp Application and Income Exclusion Provisions of the 1990 Farm Bill - This final rule, published January 5, 1993, eliminated the need for all household members to sign a declaration of citizenship or alien status and excluded certain annual clothing allowances and general assistance vendor payments from income.

Good Cause Relief From Quality Control Error Rate Liabilities - On September 28, 1992, this final rule was published in response to changes required by Section 604 of the Hunger Prevention Act of 1988 (P.L. 100-435). The rule established procedures and time frames for State agencies to request good cause relief from potential Quality Control (QC) liabilities, the criteria considered as a basis for good cause relief, and the methodology used to determine the amount of any good cause waiver.

Waivers

In Fiscal Year 1993, requests for waivers of regulatory provisions continued at a high rate, and new requests were received in the areas of Electronic Benefit Transfer (EBT) and nutrition education. Of the 183 requests, FNS approved 154 and denied 29. Approvals provided State agencies increased flexibility in application processing, recertification, delivery of benefits, management evaluation reviews, and use of computerized reporting procedures. Waivers also were approved in connection with emergency food stamp issuance to victims of natural disasters in Florida and Illinois.

Disasters

During Fiscal Year 1993, FNS operated emergency disaster Food Stamp Programs in Missouri, Iowa and Illinois, which were affected by the flooding of the Mississippi River and other rivers in the Midwest. Assistance was provided for one or two months.

Participation and cost totals for the flooding disasters in the three States are:

FOOD STAMP PROGRAM DISASTER ASSISTANCE

<u>State</u>	<u>Households</u>	<u>Benefits</u>
Missouri	17,916	\$5,642,261
Illinois	5,307	1,463,996
Iowa	6,938	1,839,550
TOTAL	30,161	\$8,945,807

Court Suit Activity in the Food Stamp Program

During Fiscal Year 1993, 44 court suits were filed against the Food Stamp Program. Ten of these court suits were filed against USDA. There are presently 181 active cases, excluding quality control (QC) and retail/wholesale suits. Major issues involved in litigation during the year were the treatment of HUD utility payments as income, failure of State agencies to process applications in a timely manner and late payment interest charges. In April 1993, the United States Supreme Court ruled for USDA on late payment interest charges. This decision reversed earlier adverse appeals court decisions in four circuits.

Litigation regarding the quality control system and the resultant liabilities has now been completed. The only case which was pending at the end of Fiscal Year 1993 was against the Commonwealth of Massachusetts in the amount of \$1,323,864. In January 1993, the United States Court of Appeals for the First District upheld a 1992 District Court's decision awarding FNS the full amount of the billing. The Court of Appeals ruled that the statistical system used by FNS for calculating the

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error rate and corresponding liabilities was a rational one that was not arbitrarily conceived or profoundly flawed or operated in a wholly capricious manner. In June 1993, the Commonwealth of Massachusetts filed a writ for certiorari requesting a hearing from the Supreme Court.

Program Management Improvement Initiatives

The Food Stamp Program continued the joint Federal-State effort begun in 1983 to reduce errors and fraud and to increase program efficiency.

The focus of the effort is to coordinate the exchange of information among States and provide technical assistance. In Fiscal Year 1993, the following efforts were pursued in support of local level management improvement initiatives:

FNS supported a broad range of initiatives by its regional offices and State cooperating agencies. These initiatives included conferences sponsored by FNS and State agencies on topics in the areas of payment accuracy, Electronic Benefit Transfer (EBT) and corrective action. In addition, the national and regional office staff participated in a number of public interest group meetings.

In Fiscal Year 1993, FNS continued to place emphasis on the need for States to make food stamp payment accuracy a high priority. FNS actively supported State efforts toward this goal. This support included encouraging States to share resources by forming joint partnerships with other State and local agencies. States shared common problems and approaches to improving payment accuracy through these partnerships. FNS also provided technical assistance to State and local offices. This assistance included the publication of TARGET, a catalog of practices aimed at improving program management and payment accuracy.

Helping State agencies fund payment accuracy efforts was also emphasized in Fiscal Year 1993. FNS' efforts included continuing to provide enhanced administrative funding to State agencies which met specific error rate goals. In Fiscal Year 1993, FNS provided \$6,563,540 in enhanced administrative funding to five State agencies based on their error rate performance for Fiscal Year 1992. These five State agencies were Hawaii, Kentucky, North Dakota, South Dakota, and the Virgin Islands. In addition, twenty-two State agencies agreed to resolve potential quality control liabilities for Fiscal Years 1986-1991 by investing approximately \$45 million in program operational improvements specifically designed to reduce errors measured by the quality control system over the next five years.

The State Exchange Project, an important component of the management improvement initiative, is based on the premise that State and local agencies can often best solve their problems by sharing in the experience of other State and local agencies. State Exchange funding was first provided in 1983 to reimburse State agency officials for the cost of visiting another State agency with known expertise in a particular area. In Fiscal Year 1993, \$349,000 in State Exchange funding was allocated for State agencies.

Electronic Benefit Transfer (EBT) Systems

In July 1993, the Secretary announced a policy of initiating EBT in all States by the end of 1996. There are currently 6 EBT systems in operation: Reading, Pennsylvania; Albuquerque, New Mexico; Ramsey County, Minnesota; Maryland (statewide); Cedar Rapids, Iowa; and Dayton, Ohio. Iowa implemented its system which is voluntary for recipients in June 1993 and Maryland completed its statewide expansion in April 1993. New Mexico is in the process of expanding statewide. Approximately 30 other State agencies have some EBT activity underway, ranging from early planning through system design and development.

A "smart card" or off-line demonstration project is operating in Dayton, Ohio. This project was fully implemented in June 1992 and will be the subject of an evaluation scheduled for release in 1994. Ohio is currently planning to expand that system statewide. Wyoming has received approval to implement an off-line demonstration project for food stamps and WIC benefits; this also will be the subject of an FNS evaluation.

Massachusetts Quarterly Demonstration Project

In 1992, the Department approved this project which allows Massachusetts to issue food stamp benefits Statewide on a quarterly basis to SSI elderly and disabled recipients who receive \$10.00 in monthly food stamp benefits. Project operations began in July 1992 and will end in July 1995.

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Welfare Simplification and Coordination Advisory Committee

The Welfare Simplification and Coordination Advisory Committee was established in December 1990 by the Mickey Leland Memorial Domestic Hunger Relief Act. Congress charged the 11-member Committee with identifying barriers to participating in more than one assistance program. The Committee was also to examine the policies and procedures which make it difficult to administer the Food Stamp, Aid to Families with Dependent Children, Medicaid, and housing assistance programs efficiently and effectively.

On July 1, 1993, the Committee submitted its report to Congress and the Secretaries of Agriculture, Health and Human Services, and Housing and Urban Development. The report, entitled Time for A Change: Remaking the Nation's Welfare System concluded that changes to the current system must be made now to reverse the trend toward more complexity and confusion and to replace it with a simpler and more responsive system. The report's primary recommendation is to replace the numerous programs that currently serve needy individuals with one family-focused, client-oriented, comprehensive program. Interim recommendations include: coordinate congressional activities involving public assistance programs; ensure that all low-income Americans have access to quality health care; establish uniform eligibility rules and definitions for all needs-based programs; expand demonstration project authority; use the success of individuals and families in achieving self sufficiency in measuring the success of programs; establish uniform implementation dates for changes in programs, encourage States to form public/private partnerships to meet clients' needs; establish a single employment and training program; streamline the verification process; use a single case manager for all programs; permit the sharing of client information among agencies; and make information on eligibility more readily available.

The response to the report was favorable and all 1,400 printed copies of the report were distributed. The submission of the Committee's report signaled the conclusion of the Committee's activities.

Collection of Claims Against Recipients

State agencies are required to establish claims against households which receive more benefits than they are entitled to receive. Two categories of claims cover household failure to report information about their circumstances. These categories are intentional program violation (IPV) and inadvertent household error claims. A third category of claims covers State agency administrative errors. As an incentive for collecting claims, State agencies can retain 25 percent of collections of IPV Claims and 10 percent of collections of inadvertent household error claims. In Fiscal Year 1992, State agencies collected \$108.3 million in recipient claims.

In Fiscal Year 1991, the Department initiated a test of collecting IPV and inadvertent household error claims from Federal income tax refunds. In its first year, this test involved two States and collections totalled about \$3.5 million during calendar year 1992. In calendar year 1993, seven additional States began participating and collections totalled about \$8.5 million. Twelve new States will be added in calendar year 1994.

In Fiscal Year 1993 FNS contracted with KPMG Peat Marwick to develop prototype standard accounting procedures for recording, maintaining and reporting food stamp recipient claims account receivables at the State level. These receivables are overpayments in the above described categories, and represent amounts due to FNS. In the first two quarters of Fiscal Year 1994 KPMG Peat Marwick will be traveling to selected states to review current accounting procedures used to process and report on food stamp recipient claims. The contractor will use this information and a review of current Federal accounting standards to develop and deliver the prototype standard procedures by the end of Fiscal Year 1994.

Error Rate Liability System and Enhanced Funding

For Fiscal Year 1992, the combined payment error rate, which combines overpayment and underpayments, was 10.69 percent. The combined payment error rate was 9.30 percent in Fiscal Year 1991.

During Fiscal Year 1992, five State agencies qualified for approximately \$6.5 million in enhanced funding made available by statute because they achieved low error rates.

For Fiscal Year 1992, twelve State agencies were notified of potential liabilities totaling \$258,488,143. The Mickey Leland Childhood Hunger Relief Act affected the Food Stamp Program's quality control system retroactive to Fiscal Year 1992. Among

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the provisions contained in that Act are a revision in the error rate tolerance and changes in the method used to calculate the claims against State agencies that exceed error rate tolerances. The revised liabilities total \$117,094,304. Potential liabilities against California (\$658) and Iowa (\$657) were waived based upon a determination that pursuit of these small claims is not in the best interest of the Food Stamp Program.

The potential liabilities for Fiscal Years 1986 through 1991 were resolved under a settlement agreement reached January 19, 1993. Most State agencies will invest 15 percent of their total liability amounts in program operational improvements specifically designed to reduce errors measured by the quality control system over the next five years; the remainder of the liabilities will be waived. One State agency will invest 10 percent of its liabilities, one State agency made a cash payment of 35 percent for its liability under an earlier settlement offer, and two State agencies made cash payments for their 15 percent liability amounts.

Error Reduction

Over and underpayments to Food Stamp recipients have been a problem that FNS has worked on for years. Until Fiscal Year 1992, steady progress was made reducing the percent of benefits issued in error (see table below). However, a variety of factors, including State budget cuts, the increase in food stamp caseload and ineffective State administration increased error rates in Fiscal Year 1992. The total amount of over and underpayment has increased, even though the percentage declined, until February 1992, due to increases in total issuance. Error rates and the losses they represent are a particular concern because overpayment dollar loss at \$1.7 billion in Fiscal Year 1992 is the largest integrity problem faced by USDA. Further, the errors create inequities for recipients. While 72 percent of households received the right amount of food stamps in Fiscal Year 1992, 18 percent received more than the law provides while 10 percent received less than they should.

FNS has made error reduction a high priority for years. The agency completes error assessment through a statistical sampling system in every State called the Quality Control (QC) system. Based upon QC data, FNS sanctions those States with the highest error rates and offers additional funding to those with the very lowest error rates. FNS has negotiated plans with States to allow the "reinvestment" of liabilities into error reduction activities. Most importantly, technical assistance is provided to States to help them develop corrective action. The transfer of best practices between States is facilitated by FNS through providing special funding that allows State officials to travel and see other States' operations. FNS has also worked with States and DHHS to reduce the complexity of the program and increase its conformity with AFDC, which should help reduce errors.

	FY 1982	FY 1986	FY 1987	FY 1988	FY 1989	FY 1990	FY 1991	FY 1992	% Change FY 82-92
Stamps in Billions	\$10.2	\$10.6	\$10.5	\$11.1	\$11.7	\$14.2	\$17.3	\$20.9	104.9
Issued In Error	\$ 1.2	\$ 1.1	\$ 1.1	\$ 1.1	\$ 1.1	\$ 1.4	\$ 1.6	\$ 2.2	83.3
Error Rate By FNS Region:									
Northeast	14.5	11.0	12.0	12.0	13.7	13.0	9.9	10.1	-30.3
Midwest	11.0	10.8	10.0	10.2	10.0	10.5	10.2	11.0	0
Western	11.8	10.4	10.2	10.5	10.0	10.4	10.0	10.6	-10.2
Southwest	12.4	12.1	10.5	10.0	9.9	9.9	9.9	10.6	-14.5
Southeast	11.3	10.1	11.0	9.6	8.7	8.5	8.6	12.5	10.6
MidAtlantic	11.8	8.9	9.4	8.6	8.1	8.2	7.8	8.7	-26.3
Mountain Plains	11.2	7.1	7.3	8.2	9.2	8.0	7.8	8.6	-23.2
U.S. Total	12.0	10.4	10.2	9.9	9.8	9.8	9.3	10.7	-10.8

Employment and Training Program

The Food Security Act of 1985 required State agencies to establish a Food Stamp Employment and Training (E&T) Program by April 1, 1987. The program is designed to improve food stamp recipients' ability to gain employment, thereby increasing earnings and reducing dependency on public assistance. State agencies operate a variety of employment and training activities, including job search and job search training, self-employment activities, and vocational and education activities.

As a condition of eligibility for food stamp benefits, applicants who are not specifically exempted by the Food Stamp Act must register for work at the time of application for benefits. Certain other 196X work registrants are exempted from E&T participation by State agencies. Work registrants are the most job ready of the food stamp population and comprise approximately 8 percent of all food stamp recipients.

In Fiscal Year 1993, State agencies reported 6,244,052 new work registrants. Of the applicants required to register for work in Fiscal Year 1993, 1,193,808 were regarded as mandatory participants. An additional 118,419 work registrants volunteered to be placed into E&T components. State agencies issued 442,657 Notices of Adverse Action (NOAA) to recipients who did not comply with work registration requirements.

There are three categories of Federal funding. In Fiscal Year 1993, State agencies spent the following amounts in each category: (1) the entire \$75 million allotted in 100 percent federally-funded grants; (2) \$61.8 million in Federal funding to match additional administrative costs incurred by the State agencies; and (3) \$21.2 million for the cost of reimbursing participants for transportation and dependent care expenses incurred in fulfilling their E&T obligations.

Optional Workfare

Optional workfare programs, which operate separately from Employment and Training programs, require able-bodied recipients to perform work in public service jobs in exchange for their food stamp allotments. In Fiscal Year 1993, 12 communities were operating Optional Workfare Programs.

E&T/JOBS Conformance Demonstration Projects

The E&T/JOBS Conformance Demonstration Project began October 1, 1992. Five State agencies were chosen to participate in the project to demonstrate the effectiveness of conforming the E&T Program and the JOBS Program. The participants are currently at various levels of operation, with two State agencies implementing their projects in Fiscal Year 1993. Georgia implemented its demonstration in four designated counties on April 1, 1993. South Dakota began its project in all twenty counties served by E&T on April 1, 1993. Expanded support services for participants were implemented in June 1993. Three State agencies--Hawaii, Missouri, and Texas--did not implement their projects during Fiscal Year 1993; however, Texas implemented its demonstration in McLennan County on October 1, 1993.

Compliance Branch Investigative Activity

During Fiscal Year 1993, with an increased emphasis on detecting trafficking, the Compliance Branch found trafficking occurring in 841 investigations, an increase of 78 (approximately 10 percent) over Fiscal Year 1992. A major activity during Fiscal Year 1993 involved the continued promotion of Federal civil prosecution of Compliance Branch trafficking cases under the Federal False Claims Act. Civil prosecutive actions were initiated in 24 U.S. District Courts. 82 settlements totaling \$1.1 million were negotiated with violating retailers in Fiscal Year 1993.

The Compliance Branch investigated 4,644 stores in Fiscal Year 1993. Of those stores investigated, 2,147 or 46 percent revealed violations of program regulations. Violations serious enough to warrant disqualification or civil money penalties were uncovered in 1,387 stores, or 30 percent of the total investigated. Stores with less serious violations received an official warning letter, a record of which is maintained as part of their file on program participation.

Retailer Reauthorizations

The FACT Act provided for the periodic reauthorization of all food stores participating in the Food Stamp Program. This reauthorization process includes: determining the continued eligibility of stores, as well as updating the retailer data base with information regarding store characteristics, ownership and related identifying information, sales information and key eligibility factors. This

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database is the primary tool used by FNS to monitor over 207,000 firms and identify potential violators for investigation. Thus, it is critical that information on stores be updated at least once every two years.

For the Fiscal Year 1992-1993 cycle, FNS reauthorized 160,000 firms to participate in the Food Stamp Program, and withdrew 35,000 firms because they no longer met authorization criteria or failed to cooperate and provide information to make a determination. FNS has begun a new reauthorization cycle in Fiscal Year 1994.

Expedited Service Cash-Out Demonstration Projects

In 1990, the Department gave approval to Minnesota and Vermont to implement projects which provide cash benefits to households eligible for expedited service. In Minnesota, an expedited service household receives 25% of its first month benefits in cash; the remainder is in coupons. Vermont provides the full first month allotment in cash. Minnesota implemented its project in September 1990 and the evaluation has been completed. The results of the project include: cashout enabled Minnesota to centralize benefit issuance which provided significant advantages in efficiency and administrative expenditures at the county, State, and Federal levels; program participants indicated a high level of satisfaction with cashout and there was very minimal client inconvenience; and misuse of the benefit check, such as purchasing nonfood items, is properly controlled. Vermont implemented its project in 1991; the evaluation has not been completed.

"Welfare Reform" Demonstration Projects

In Fiscal Year 1993, FNS approved five welfare reform proposals involving food stamp waivers in Iowa, Maryland, Vermont, Virginia, and Wisconsin. Of the newly-approved proposals, only the Wisconsin proposal included a cash-out component.

Six welfare reform projects were underway prior to Fiscal Year 1993, including projects in Alabama, Michigan, Minnesota, New York, Ohio, and Utah. A separate cash-out only project continues to operate in San Diego County, California.

The Food Stamp Program aspect of the Washington Family Independence Project ended June 30, 1993 after five years of operation. The project, which tested cashing out food stamp benefits, yielded the following results: households spent less on food which lowered the nutrient availability of several nutrients, although the majority of households still exceeded the Recommended Daily Allowance (RDA) levels for most nutrients.

Welfare reform proposals submitted to FNS may not restrict eligibility for food stamp benefits or reduce benefit amounts. Proposals must also contain provisions to evaluate the effectiveness of the demonstration project.

Anti-Fraud Funding for State Agencies

In Fiscal Year 1993, \$93.1 million was available to State agencies for anti-fraud activity. Anti-fraud funding is designed to cover not less than 75 percent of State agencies' costs in the area of investigation and prosecution of fraud cases and the collection of fraud claims. In Fiscal Year 1993, a total of 53 State agencies were approved for 75 percent enhanced funding. Of these, 43 State agencies had agreements with State or local prosecutors to facilitate the prosecution of cases and the imposition of food stamp disqualifications. During Fiscal Year 1992, the last year for which we have complete data, approximately 30,000 persons were disqualified from the program as a result of prosecutions, and 42,000 were disqualified through administrative hearings.

Information on Persons Disqualified from the Food Stamp Program

FNS implemented a redesigned computer matching program to collect and disseminate information on individuals who have been disqualified from participation in the Food Stamp Program for Intentional Program Violations. Disqualification data is submitted by the State welfare agencies to the FNS-maintained database which in turn is available to all State welfare agencies for program enforcement purposes. Currently, 40 State welfare agencies are eligible to participate with the remainder expected to be on board by April 1994.

Program Responsiveness

In Fiscal Year 1993, FNS awarded more than \$1.7 million to 16 nonprofit organizations to conduct a series of demonstration projects designed to examine ways to improve program responsiveness. These projects target members of rural, elderly, and homeless populations; low-income working families with children; non-English

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speaking minorities; and Native Americans. The demonstration projects will test many different approaches such as one-on-one application assistance, transportation to the local office, alternate hours to learn about the program and to file applications, and translation services. All grantees will be creating various types of informational materials to help alleviate misconceptions about program requirements. An independent evaluation firm will be reviewing the effectiveness of the approaches being tested.

Legislation

In Fiscal Year 1993, four public laws were approved that affect the program:

- o P.L. 102-586, the Juvenile Justice and Delinquency Prevention Act Amendments, approved November 4, 1992, exempted any funds designated for Child Care Block grants from being counted as income for any other Federal programs that base eligibility on need, including the Food Stamp Program.
- o P.L. 103-11, approved April 1, 1993, delayed, from April 1, 1993 to January 31, 1994, implementation of a P.L. 102-237 requirement to stagger food stamp issuance for families living on Indian reservations and a prohibition against requiring such households to report monthly on household circumstances.
- o P.L. 103-31, the National Voter Registration Act of 1993 approved May 20, 1993, required that all offices in a State that provide public assistance (including food stamp offices) must distribute mail voter registration application forms; must assist applicants in completing applications, unless such assistance is refused; and accept completed applications for transmittal to the appropriate State election official. P.L. 103-31 is effective January 1, 1995, but would be effective January 1, 1996, or later, in States that must approve constitutional amendments in order to comply.
- o P.L. 103-66, the Omnibus Budget Reconciliation Act of 1993, Chapter 3 of which is the Mickey Leland Childhood Hunger Relief Act, approved August 10, 1993, contained the following provisions:
 - Excluded as income of the household, earnings of elementary or high school students who are members of the household and are 21 years old or younger.
 - Eliminated the shelter deduction cap in increments. The cap would be \$231 from July 1, 1994, through September 30, 1995 (\$402 for Alaska, \$330 for Hawaii, \$280 for Guam, and \$171 for the Virgin Islands); \$247 from October 1, 1995, through December 31, 1996 (\$429 for Alaska, \$353 for Hawaii, \$300 for Guam, and \$182 for the Virgin Islands); and no cap beginning January 1, 1997.
 - Excluded earned income tax credits (EITCs) as resources for 12 months from receipt if the individual receiving the EITC was participating in the FSP when the EITC was received and participates continuously during the 12-month period.
 - Excluded as income entire amount of vendor payments for transitional housing for the homeless.
 - Revised the provision on counting general assistance (GA) vendor payments as income so that only those vendor payments provided to cover housing expenses, exclusive of energy or utility expenses, are included as income.
 - Eliminated proration of benefits for households unless they are off the FSP for more than 1 month.
 - Increased Puerto Rico's Nutrition Assistance Program authorized funding by \$6 million for Fiscal Year 1994 and \$10 million for Fiscal Year 1995.
 - Gave State agencies the option to provide a deduction for legally-binding child support payments made to nonhousehold members. By October 1, 1995, the deduction would become mandatory. Authorized the Secretary to establish in regulations the methods (which may include retrospective budgeting) to be used to determine the amount of the deduction.
 - Raised the cap on the dependent care deduction from \$160 to \$200 for children under 2 years old and \$175 for all other dependents.

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- Removed the specific dollar cap on dependent care reimbursements under the Employment and Training Program; required the use of applicable local market rate (using procedures consistent with the aid to Families with Dependent Children's Job Opportunities and Basic Skills Training Program) instead, but that rate must be at least \$200 for children under 2 and \$175 for all other dependents. Provided 50 percent Federal funding for amounts State agencies reimburse up to the applicable market rate.
- Set the fair market value of vehicles which is excluded in determining households' resources at \$4,550 for September 1, 1994 - September 30, 1995 and \$4,600 for October 1, 1995 - September 30, 1996. From October 1, 1996, the value will be adjusted annually using \$5,000 as a base and the CPI-U for new cars for the 12 months ending the preceding June and rounding to the nearest \$50.
- Excluded as resources, the value of vehicles used to carry the primary source of fuel for heating or water for home use.
- Mandated that the Department conduct demonstration projects testing allowing food stamp households to accumulate up to \$10,000 in resources without losing their food stamp eligibility. Limited the demonstration projects to 4 years duration (beginning after September 30, 1993) and 11,000 households. Required households to maintain the additional resources in separate accounts and required that the resource be intended for one of the following purposes: (1) improving the education, training, or employability (including self employment) of household members, (2) purchasing a home for the household, (3) changing the household's residence, and (4) making major repairs to the household's home.
- Simplified the household definition: children 21 years old and under living with their parents cannot be separate households from their parents unless they are married and living with their spouses and/or living with their children; children (other than foster children) who are under 18 years old and live under the parental control of an adult household member cannot be separate households; adult siblings who live together and adult children who live with their parents can be separate households if they purchase and prepare food separately; retained the Fenwick provision for separate household status of elderly, disabled people.
- Permitted the children of drug addicts and alcoholics who live with their parents in treatment centers to qualify for food stamps. Made the meals served to those children by the centers eligible for purchase with food stamps.
- Effective October 1, 1993, expanded the disclosure provision to permit collection of claims resulting from intentional program violations and inadvertent household errors by offsetting Federal pay. Authorized such claims collection.
- Disqualified recipients for 1 year for a first finding by a court that the recipient has purchased illegal drugs with food stamps and permanently for a second such finding or the first finding by a court that the recipient has purchased firearms, ammunition, or explosives with food stamps.
- Effective October 1, 1993, raised the cap on civil money penalties for trafficking to \$40,000 per investigation.
- Effective October 1, 1993, raised the cap on civil money penalties for selling firearms, ammunition, or explosives for food stamps to \$40,000 per investigation.
- Modified the quality control (QC) system retroactive to October 1, 1991 to:
 - Permit interest to accrue if bills are not paid after 1 year;
 - Use each year's national performance measure to establish a State agency's liability;
 - Calculate a State agency's liability by multiplying its issuance times the ratio of the amount the State agency's payment error

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- rate exceeds the national performance measure to the national performance measure (but not greater than 1) times the amount the State agency's payment error rate exceeds the national performance measure;
- Require that all case reviews and arbitrations be completed by March 29 (or March 28 in leap years) and require the Department to determine final error rates, the national average payment error rate, and billing amount by April 28 (or April 27 in leap years);
- Require that good cause determinations be made by administrative law judges (ALJs) rather than the Secretary;
- Provide the following timeframes relative to the ALJs' determination of billing amounts:
 - 10 days after the billing for the State agency to request an appeal
 - 60 days for the State agency to submit evidence in support of its appeal
 - 60 days for the Department to respond
 - 30 for State agency rebuttal, if any
 - 60 days after the submission of the State agency's rebuttal for the ALJs' decision or, if there is no rebuttal, 90 days after the State agency's original submission of evidence (60 of which are available to the Department for the preparation of its response)
 - Authorize the ALJs to extend any of the above deadlines
 - Retroactive to October 1, 1991, require the ALJs to hold evidentiary hearing upon the request of either the State agency or the Department
 - Define "good cause" to include:
 - a natural disaster or civil disorder that adversely affects FSP operations
 - a strike by State agency employees who make eligibility determinations or process changes
 - significant growth (e.g., 15%) in a State's caseload
 - a FSP change or other Federal or State program change that substantially or adversely impacts FSP management
 - a significant circumstance beyond the control of the State agency.
- Modified the quality control (QC) system retroactive to October 1, 1992 to:
 - Exclude errors made in applying a new regulation for a 120-day period following the required implementation date (rather than 60 or 90 days);
- Effective April 1, 1994, provided 50 percent Federal funding for State agencies' administrative costs for automation, fraud investigations and prosecutions, and the Systematic Alien Verification for Entitlement system. Provided for later implementation for States whose legislatures do not have a regular session in Calendar Year 1994 and that have no mechanism under constitutions or State laws for appropriating the necessary additional funds before the next legislative session.
- Most provisions were effective September 1, 1994, unless otherwise indicated.

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FOOD STAMP PROGRAM
SUMMARY OF BENEFIT COSTS, PARTICIPATION AND STATE ADMINISTRATIVE FUNDING
FISCAL YEAR 1993

STATE OR TERRITORY	AVERAGE PARTICIPATION IN THOUSANDS		BENEFIT VALUE OF STAMPS ISSUED (000)	AVERAGE MONTHLY BENEFIT PER PERSON	STATE ADMINISTRATIVE FUNDING (000)
	PERSONS	HOUSEHOLDS			
Alabama	560	216	\$457,048	\$68.01	\$28,935
Alaska	43	14	44,955	86.89	7,395
Arizona	489	178	393,451	67.10	26,738
Arkansas	285	106	209,192	61.16	14,111
California	2,866	1,075	2,079,026	60.45	233,747
Colorado	273	108	226,489	69.23	12,562
Connecticut	215	93	142,797	55.25	14,686
Delaware	58	21	46,451	66.87	3,874
District of Columbia	87	41	80,725	77.74	8,308
Florida	1,500	606	1,334,234	74.13	56,470
Georgia	807	315	656,978	67.81	47,866
Hawaii	103	44	131,848	106.72	5,954
Idaho	79	29	56,702	59.60	4,229
Illinois	1,178	493	1,060,128	74.98	47,259
Indiana	497	184	406,256	68.17	24,279
Iowa	196	78	146,707	62.34	8,240
Kansas	188	73	141,310	62.54	7,506
Kentucky	530	200	421,945	66.28	26,470
Louisiana	779	282	653,056	69.88	34,440
Maine	138	61	111,703	67.21	6,256
Maryland	375	159	336,430	74.86	19,207
Massachusetts	443	189	326,017	61.36	21,331
Michigan	1,022	419	837,474	68.28	42,261
Minnesota	317	131	229,377	60.30	26,237
Mississippi	537	200	416,349	64.62	17,737
Missouri	591	236	477,936	67.44	24,329
Montana	70	27	53,778	63.73	5,056
Nebraska	113	45	80,802	59.40	5,216
Nevada	93	42	85,736	76.49	4,423
New Hampshire	60	26	46,074	63.61	2,858
New Jersey	531	218	469,247	73.71	49,985
New Mexico	244	85	194,082	66.38	11,772
New York	2,045	943	1,796,148	73.19	122,411
North Carolina	627	253	479,773	63.76	32,485
North Dakota	48	19	35,704	61.56	3,335
Ohio	1,269	535	1,101,172	72.30	66,902
Oklahoma	370	146	293,721	66.10	19,159
Oregon	283	123	234,855	69.19	17,342
Pennsylvania	1,186	518	960,882	67.51	84,173
Rhode Island	92	40	72,973	65.77	5,478
South Carolina	394	146	305,550	64.58	17,586
South Dakota	56	20	42,571	63.42	4,063
Tennessee	774	317	611,160	65.82	26,441
Texas	2,659	975	2,239,466	70.19	126,197
Utah	133	47	97,293	61.17	9,601
Vermont	58	25	38,269	55.02	4,248
Virginia	535	225	431,556	67.25	41,023
Washington	462	191	368,608	66.42	33,236
West Virginia	322	124	260,853	67.41	6,476
Wisconsin	337	125	220,862	54.56	25,648
Wyoming	34	13	26,327	64.10	2,274
American Samoa	0	0	0	.00	0
Guam	13	4	17,790	117.41	1,744
North Mariana Island	0	0	0	.00	0
Puerto Rico	0	0	0	.00	0
Trust Territory	0	0	0	.00	0
(excluding NM)	0	0	0	.00	0
Virgin Islands	18	5	19,375	92.21	3,043
Indian Tribe Set Asi	0	0	0	.00	0
Indian Tribes	0	0	0	.00	0
Freely Associated States	0	0	0	.00	0
DDO Army/AF/USMC/Navy	0	0	0	.00	0
Anticipated Adjustment	0	0	0	.00	-41,452
TOTAL	26,983	10,791	\$22,009,209	\$67.97	\$1,461,151

NOTE: These data are based in part on preliminary data submitted by State and local agencies subject to change as revised reports are received, and may differ from budgetary information appearing elsewhere in these notes. Totals may not add due to rounding.

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FOOD STAMP PROGRAM
FIRMS AUTHORIZED TO RECEIVE AND REDEEM FOOD STAMPS

Fiscal Year 1993

STATE OR TERRITORY	RETAILERS	WHOLE- SALEERS	MEALS/ WHEELS	COMM DINE	ALCOHOL, DRG TREAT & COMB TREAT	PRIVATE REST	GROUP LIV	HOMELESS MEAL/ BATTERED WOMEN & CHILDREN	TOTAL
Alabama-----	5,001	5	1	28	9	0	2	1	5,047
Alaska-----	493	3	4	4	2	0	0	0	506
Arizona-----	2,163	9	21	30	11	1	0	4	2,239
Arkansas-----	2,907	5	10	36	7	0	0	2	2,967
California-----	16,819	46	2	14	113	0	5	9	17,008
Colorado-----	1,757	8	25	25	8	0	0	5	1,828
Connecticut-----	1,729	7	9	7	10	0	0	0	1,762
Delaware-----	515	0	4	5	1	0	0	0	525
District of Columbia-----	566	0	5	2	2	0	0	0	575
Florida-----	11,106	25	33	76	43	4	15	7	11,309
Georgia-----	6,587	2	12	75	5	15	0	7	6,703
Hawaii-----	1,112	11	2	4	9	19	0	0	1,157
Idaho-----	744	0	10	13	0	0	1	2	770
Illinois-----	7,081	9	58	63	11	2	0	11	7,235
Indiana-----	3,099	3	27	15	1	2	1	2	3,150
Iowa-----	1,895	1	25	12	0	0	0	1	1,934
Kansas-----	1,528	3	14	15	12	0	0	1	1,573
Kentucky-----	5,268	3	3	9	3	0	0	0	5,286
Louisiana-----	6,021	10	18	45	3	0	1	9	6,107
Maine-----	1,941	2	12	44	6	15	4	0	2,024
Maryland-----	3,295	18	19	23	17	0	2	2	3,376
Massachusetts-----	3,875	3	18	13	11	6	1	0	3,927
Michigan-----	7,799	10	19	54	13	7	2	0	7,904
Minnesota-----	3,174	3	61	29	6	1	0	3	3,277
Mississippi-----	4,561	1	7	11	0	0	1	0	4,581
Missouri-----	3,714	0	25	78	0	0	0	3	3,820
Montana-----	814	0	6	25	0	0	0	0	845
Nebraska-----	977	1	1	6	1	0	0	1	987
Nevada-----	522	4	0	8	4	0	0	1	539
New Hampshire-----	881	0	4	7	3	0	1	0	896
New Jersey-----	5,161	12	36	24	19	0	3	0	5,255
New Mexico-----	1,237	2	11	15	1	0	1	0	1,267
New York-----	14,864	19	85	140	70	87	5	7	15,277
North Carolina-----	7,140	2	43	76	9	0	1	4	7,257
North Dakota-----	645	1	40	42	0	0	1	1	730
Ohio-----	7,319	1	49	64	6	1	0	2	7,442
Oklahoma-----	3,095	7	9	29	6	0	0	0	3,146
Oregon-----	2,448	3	14	20	8	2	1	5	2,501
Pennsylvania-----	10,448	26	114	95	46	1	2	9	10,741
Rhode Island-----	838	2	3	5	3	0	1	0	852
South Carolina-----	4,152	0	12	55	7	0	0	2	4,228
South Dakota-----	629	0	7	16	0	1	0	0	653
Tennessee-----	5,513	13	15	25	14	0	4	3	5,587
Texas-----	15,667	26	17	64	26	1	7	22	15,830
Utah-----	834	8	7	9	13	0	0	2	873
Vermont-----	764	2	6	1	2	0	0	0	775
Virginia-----	5,559	6	13	32	14	0	0	1	5,625
Washington-----	3,321	3	26	41	3	0	0	4	3,398
West Virginia-----	2,755	0	20	47	0	0	0	3	2,825
Wisconsin-----	2,766	1	20	33	0	0	0	3	2,823
Wyoming-----	327	0	4	1	0	1	1	1	335
Guam-----	220	0	0	0	0	0	0	0	220
Virgin Islands-----	208	0	1	2	0	4	0	0	215
TOTAL-----	203,854	326	1,007	1,612	558	170	63	140	207,730

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SUMMARY OF QC LIABILITIES AND ENHANCED FUNDING

QC PERIOD	MAX'L GOAL/ TOLERANCE (%)	ENHANCED FUNDING NUMBER OF STATES	ENHANCED FUNDING AMOUNT AWARDED	LIABILITY NUMBER OF STATES	TOTAL INITIAL LIABILITIES	QC COLLECTIONS	OUTSTANDING AND POTENTIAL LIABILITIES
Oct 1980 - Mar 1981	12.60	7	\$ 1,406,436	14	\$ 16,709,031	\$0	\$0
Apr 1981 - Sept 1981	12.60	8	\$ 5,288,070	12	\$ 12,256,197	\$1,372,228	\$0
Oct 1981 - Mar 1982	13.05	6	\$ 2,488,142	12	\$ 9,072,985	\$1,574,522.56	\$0
Apr 1982 - Sept 1982	13.05	7	\$ 2,700,139	9	\$ 6,811,989	\$0	\$1,323,864.2
FY 1983	9.00 1	1	\$ 383,252	12	\$ 12,628,093	\$1,058,131.20	\$0.3
FY 1984	7.00 1	2	\$ 744,601	36	\$ 81,350,280	\$ 558,503	\$0.3
FY 1985	5.00 1	3	\$ 1,100,245	48	\$201,168,802	\$ 299,390	\$0.3
FY 1986	11.39	3	\$ 1,175,006	14	\$ 45,868,754	\$6,576,096.4	\$0
FY 1987	11.27	4	\$ 2,173,455	10	\$ 42,592,970	\$6,306,946.4	\$0
FY 1988	10.97	2	\$ 985,962	8	\$ 34,775,467	\$5,216,320.4	\$0
FY 1989	10.80	7	\$ 7,150,142	8	\$ 56,428,400	\$8,464,260.4	\$0
FY 1990	10.80	5	\$ 6,956,616	11	\$ 64,727,769	\$9,709,165.4	\$0
FY 1991	10.31	5	\$ 9,422,364	11	\$ 55,953,052	\$8,392,958.4	\$0
FY 1992	10.69 3	5	\$ 6,563,540	12	\$117,095,619	\$0.5	\$117,094,304.5
TOTALS			\$48,525,970		\$757,419,408	\$49,560,519.76	\$118,418,168

1 Excludes underinsurance error rates.

2 The only outstanding QC liability is a sanction in the amount of \$1,323,864 owed by the State of Massachusetts for April-September 1982. The State agency has been billed; collection is pending.

3 Revestment of the 1990 Frew Bill eliminated all remaining outstanding balances for Fiscal Years 1983 through 1985.

4 Under a settlement reached January 19, 1993, most States will invest 1% of their total liability amounts for FY 1986 1991 in program operational improvements specifically designed to reduce errors measured by the quality control system over the next 5 years; the remainder of the liabilities will be waived. One State will invest 10% of its liability; one State made a cash payment of 3% of its liability under an earlier settlement offer, and two State agencies made cash payments for their 1% liability amounts.

5 Notices of potential liabilities were issued on June 30, 1993. FY 1993 national error rate goal and potential liability amounts were revised on 8/11/93 as a result of legislative changes contained in the Mickey Leland Childhood Hunger Relief Act of 1993. The potential liabilities against California (\$558) and Iowa (\$657) were waived based upon a determination that pursuit of these small claims is not in the best interest of the Program.

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THE FOOD AND NUTRITION SERVICE

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

Nutrition Assistance for Puerto Rico:

For monthly payments to the Commonwealth of Puerto Rico for nutrition assistance, as authorized by 7 U.S.C. 2028, \$1,143,000,000.

This change provides a separate appropriation for Nutrition Assistance for Puerto Rico. Comparable language was deleted from the appropriation for the Food Stamp Program.

31-54

NUTRITION ASSISTANCE FOR PUERTO RICO

Appropriations Act, 1994	\$1,091,000,000
Budget Estimate, 1995	1,143,000,000
Increase in Appropriation	<u>+52,000,000</u>

SUMMARY OF INCREASES AND DECREASES
(On basis of appropriation)

Item of Change	1994 Estimated	Other Changes	1995 Estimated
Nutrition Assistance for Puerto Rico.....	<u>\$1,091,000,000</u>	<u>+\$52,000,000</u>	<u>\$1,143,000,000</u>

PROJECT STATEMENT - CURRENT LAW
(On basis of adjusted appropriation)

Project	1993 Actual	1994 Estimated	Increase or Decrease	1995 Estimated
Nutrition Assistance for Puerto Rico.....	\$1,051,000,000	\$1,091,000,000	+\$52,000,000	\$1,143,000,000
Funds available to: Animal and Plant Health Inspection Service...a/.....	-10,825,000	-12,472,000	+12,472,000	—
Total, Available or: Estimate.....	1,040,175,000	1,078,528,000	+64,472,000	1,143,000,000

a/ Funds available through appropriations transfer in Fiscal Years 1993 and 1994 and through reimbursement in Fiscal Year 1995.

EXPLANATION OF PROGRAM

Overview of Program Development. Authorized by section 116(a) of the Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35), a grant for nutrition assistance to Puerto Rico was implemented July 1, 1982. The Food, Agriculture, Conservation and Trade Act of 1990 (FACT), P.L. 101-624, enacted November 28, 1990, reauthorized appropriations through Fiscal Year 1995. The Omnibus Budget Reconciliation Act of 1993 (P.L. 103-66) enacted August 10, 1993, increased the authorized levels for Fiscal Years 1994 and 1995.

Eligibility. This grant, which replaced the Food Stamp Program in Puerto Rico, gives the Commonwealth broad flexibility to establish a food assistance program that is specifically tailored to the needs of its low-income households. In Fiscal Year 1995, Puerto Rico will continue its system of providing cash benefits to households which meet eligibility standards of the Nutrition Assistance Program. These eligibility standards are similar to those of the Food Stamp Program.

Benefits. In addition to the provision of direct benefits to the needy, a portion of the grant may be used to fund up to 50 percent of the costs of administering the program.

State/Federal Responsibilities. The Commonwealth must submit its annual plan of operation to the Secretary for approval. The Food and Nutrition Service provides a grant award to the Commonwealth to operate the Program in accordance with its approved plan. The grant is intended to cover 100 percent of the cost of program benefits and 50 percent of the cost of administrative expenses.

JUSTIFICATION OF INCREASES AND DECREASES

An increase of \$52,000,000 in the appropriation for Nutrition Assistance for Puerto Rico (\$1,091,000,000 available in 1994).

Need for Change. This request reflects the authorization level provided in the Omnibus Budget Reconciliation Act of 1993, Public Law 103-66.

Nature of Change. This level will permit the continuation of the Nutrition Assistance Program in a manner consistent with prior years.

31g-41

NUTRITION ASSISTANCE FOR PUERTO RICO

STATUS OF PROGRAM

As required by P.L. 97-35, the Omnibus Budget Reconciliation Act of 1981, the Food Stamp Program in the Commonwealth of Puerto Rico was replaced with a block grant effective July 1, 1982.

For Fiscal Year 1993, \$1.040 billion in grant funds were provided to Puerto Rico. The Nutrition Assistance Program served an average of 1.44 million persons per month. Total benefit costs are estimated at \$1,011 million, or about \$58.41 per person per month. Administrative costs are estimated at \$29.149 million, or \$1.69 per person, for a total Federal program cost per person of \$60.10 per person per month. One special project, tick eradication, was budgeted at a cost of \$10.825 million. Congress mandated that \$10.825 million be transferred to the Animal and Plant Health Inspection Service for use by Puerto Rico in operating this program in Fiscal Year 1993. The objective of the Tick Eradication Project is to carry out appropriate treatment and control activities directed toward the enhancement of livestock productivity through the island-wide eradication of ticks. The Commonwealth is also operating a Special Wage Incentive Program, budgeted at \$21.1 million of the Federal grant for Fiscal Year 1994, which provides wage subsidies to employers hiring Nutrition Assistance Program recipients.

Selected Examples of Recent Progress:

Puerto Rico submits its proposed annual budget plan in July for the fiscal year beginning on the following October 1. That plan identifies the costs of benefits, administration and other projects. Actual costs of these components for 1991 and 1992 and preliminary final costs for 1993 are as follows:

	1991	1992	1993
	<u>Actual</u>	<u>Actual</u>	<u>Preliminary Final</u>
	(\$ in thousands)		
Benefits costs	\$935,394	\$972,561	\$1,011,026
Administrative costs ..	27,017	29,614	29,149
Cattle Tick Eradication Project	<u>10,825</u>	<u>10,825</u>	<u>10,825</u>
Total, Federal funds ..	973,236	1,013,000	1,051,000
State Administrative costs	<u>27,017</u>	<u>29,614</u>	<u>29,149</u>
Total program costs ...	\$1,000,253	\$1,042,614	\$1,080,149

From its inception, the Food Stamp Program in Puerto Rico served a much higher proportion of total population than was true of the U.S. as a whole, due to the significantly lower living standards in Puerto Rico. This continues to be the case under the block grant program: 1.44 million or 42.3 percent of Puerto Rico's total estimated population of 3.4 million people participated in the program in 1993. Monthly participation and estimates for 1991, 1992, and 1993 are as follows:

	1991	1992	1993
	<u>Actual</u>	<u>Actual</u>	<u>Preliminary Final</u>
Average number of persons (millions)	1.49	1.48	1.44
Average number of households	494,142	500,169	493,227
Average household size	3.02	2.96	2.92
Average benefits per household ...	\$158	\$162	\$170

In Fiscal Year 1993 Puerto Rico spent an estimated \$29.1 million of Federal money on administrative activities, and an equivalent amount of State funds since there is a 50:50 matching requirement for these costs.

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Federal Responsibilities. FNS provides funds intended to cover 100 percent of the benefit costs and 50 percent of the administrative costs of the program as appropriated by Congress. FNS must review and approve the Commonwealth's annual plan and monitor program operations to assure program integrity, etc. These monitoring activities include reviewing financial reports such as the SF-269, and on-site management reviews of selected program operations.

FOOD AND NUTRITION SERVICE

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

Food Donations [Programs] for Selected Groups:

- 1 For necessary expenses to carry out section 4(a) of the Agriculture and Consumer Protection Act of 1973 (7 U.S.C. 612c (note)), ~~section 4(b) of the Food Stamp Act~~ (7 U.S.C. 2013 (b)), P.L. 96-597 and section 311 of the Older Americans Act of 1965, as amended (42 U.S.C. 3030a), [S218,641,000] \$179,596,000 to remain available through September 30, [1995] 1996. Provided, That notwithstanding any other provision of
- 2 law, for meals provided pursuant to the Older Americans Act 1965, a maximum rate of reimbursement to States will be ~~established~~ by the Secretary, subject to reduction if obligations would exceed the amount of available funds, with any unobligated funds to remain available only for obligation in the fiscal year beginning October 1, [1994.] 1995. For necessary expenses to carry out section 110 of the Hunger Prevention Act
- 3 of 1988, [\$40,000,000] \$50,000,000.

The first change cites the authorization for providing a food assistance program in American Samoa.

The second change would make the appropriation available until September 30, 1996.

The third change would increase the appropriation above the authorization level of \$40,000,000 for Fiscal Year 1995 provided in the FACT Act (P.L. 101-624) amendments to the Hunger Prevention Act of 1988 (P.L. 100-425).

FOOD DONATIONS FOR SELECTED GROUPS - CURRENT LAW

Appropriations Act, 1994	\$256,641,000
Budget Estimate, 1995	229,596,000
Decrease in Appropriation	<u>-26,045,000</u>

SUMMARY OF INCREASES AND DECREASES
(On basis of appropriation)

<u>Item of Change</u>	<u>1994</u> <u>Estimated</u>	<u>Program</u> <u>Changes</u>	<u>1995</u> <u>Estimated</u>
Food Distribution Program on Indian Reservations:....	\$68,641,000	-\$30,187,000	\$38,454,000
Nutrition Program for the Elderly.....	150,000,000	-8,858,000	141,142,000
Commodities for Soup Kitchens.....	<u>40,000,000</u>	<u>+10,000,000</u>	<u>50,000,000</u>
Total Available.....	<u>258,641,000</u>	<u>-29,045,000</u>	<u>229,596,000</u>

PROJECT STATEMENT
(On basis of appropriation)

<u>Project</u>	<u>1993</u> <u>Actual</u>	<u>1994</u> <u>Estimated</u>	<u>Increase</u> <u>or Decrease</u>	<u>1995</u> <u>Estimated</u>
1. Food Distribution	:	:	:	:
Program on Indian	:	:	:	:
Reservations:	:	:	:	:
Commodities in lieu of	:	:	:	:
food stamps.....	\$54,405,338:	\$47,036,000:	-\$34,229,000:	\$12,807,000
American Samoa.....	—	2,700,000:	+2,600,000:	5,300,000
Distributing agencies	:	:	:	:
expenses and Nutrition:	:	:	:	:
Education.....	18,444,000:	18,905,000:	+1,442,000:	20,347,000
Subtotal, Food	:	:	:	:
Distribution Program	:	:	(1):	:
on Indian Reservations:	72,849,338:	68,641,000:	-30,187,000:	38,454,000
2. Nutrition Program for:	:	:	:	:
the Elderly:	:	:	:	:
Commodities.....	9,367,000:	9,828,000:	-\$65,000:	9,263,000
Cash in Lieu of	:	:	:	:
commodities.....	142,296,662:	140,172,000:	-8,293,000:	131,879,000
Subtotal, Nutrition	:	:	(2):	:
Program for the Elderly:	151,663,662:	150,000,000:	-8,858,000:	141,142,000
3. Commodities for Soup:	:	:	(3):	:
Kitchens.....	32,000,000:	40,000,000:	+10,000,000:	50,000,000
Total Appropriation.....	256,513,000:	258,641,000:	-29,045,000:	229,596,000

NOTE: THESE FIGURES REFLECT THE REPROGRAMMING OF \$8,751,662 FROM POPR TO NPE IN FY 1993.

PROJECT STATEMENT
(On basis of available funds)

<u>Project</u>	<u>1993</u> <u>Actual</u>	<u>1994</u> <u>Estimated</u>	<u>Increase</u> <u>or Decrease</u>	<u>1995</u> <u>Estimated</u>
1. Food Distribution Program:	:	:	:	:
on Indian Reservations:	:	:	:	:
Commodities in lieu of:	:	:	:	:
food stamps.....	\$49,643,603:	\$21,933,832:	+\$22,036,168:	\$43,970,000
American Samoa.....	:	+2,700,000:	+2,600,000:	5,300,000
Distributing agencies	:	:	:	:
expenses and Nutrition:	:	:	:	:
Education.....	18,143,348:	18,905,000:	+1,442,000:	20,347,000
Subtotal, Food Dist.	:	:	:	:
Program on Indian	:	:	(1):	:
Reservations.....	67,786,951:	43,538,832:	+26,078,168:	69,617,000

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PROJECT STATEMENT
(On basis of available funds)

Project	1993 Actual	1994 Estimated	Increase or Decrease	1995 Estimated
2. Nutrition Program for the Elderly:				
Commodities	8,074,000:	9,828,000	-565,000:	9,263,000
Cash in Lieu of commodities	142,591,217:	140,172,000	-8,293,000:	131,879,000
Subtotal, Nutrition 1/			(2):	
Program for the Elderly:	150,665,217:	150,000,000	-8,858,000:	141,142,000
3. Commodities for Soup Kitchens:			(3):	
	32,000,000:	40,000,000	+10,000,000:	50,000,000
Total Obligations	250,452,168:	233,538,832	+27,220,168:	260,759,000
Unobligated balances				
Recovery of prior year obligations	—	—	—	—
Unobligated balances	—	—	—	—
Available, start of year:	—	-6,060,832	-25,102,168:	-31,163,000
Available, end of year ..	+6,060,832:	+31,163,000	-31,163,000:	—
Expiring				
Total Appropriation	256,513,000:	258,641,000	-29,045,000:	229,596,000

1/ THESE FIGURES REFLECT THE REPROGRAMMING OF \$7,753,217 FROM FDIPIR TO NPE IN FY 1993, REFLECTING AN ADJUSTMENT OF \$998,445 IN BUDGET AUTHORITY

2/ Does not reflect the rescission of the \$6.0 million pending in Congress.

EXPLANATION OF PROGRAM

Food Donations Programs for Selected Groups includes funds for: the Food Distribution Program on Indian Reservations (FDPIR); the continuation of food assistance to the Republic of Palau; the nuclear affected areas of the Marshall Islands; the Nutrition Program for the Elderly; and commodity purchases for soup kitchens and food banks authorized by the Hunger Prevention Act of 1988 (Public Law 100-435); and provision of a nutrition assistance program in lieu of a Food Stamp Program in American Samoa.

Food Distribution Program on Indian Reservations (FDPIR)

Overview of Program Development. The Food Stamp Act of 1977 authorized the distribution of agricultural commodities to eligible needy persons residing on or near Indian reservations or in the Pacific Islands. FDPIR was provided as an alternative to the Food Stamp Program for Indian households in rural areas where the Food Stamp Program was not readily available or where food stores were inconveniently located. The Act stipulates that a food distribution program may be established on an Indian reservation if an Indian Tribal Organization (ITO) requests the program. If the ITO is capable of administering the program, it may do so in lieu of administration by a State agency. P.L. 97-98 authorized low-income Indian households residing in Oklahoma to participate in the program. The Program has been reauthorized through Fiscal Year 1995 by the Food, Agriculture, Conservation and Trade Act of 1990 (FACT), P.L. 101-624.

The Compact of Free Association Act of 1985 (P.L. 99-239), as amended by the Palau Compact of Free Association Act (P.L. 99-658), terminated the Trusteeship Agreement with the Federated States of Micronesia and the Marshall Islands and established them as Freely Associated States. For transition purposes, food assistance continued through Fiscal Year 1989 but at reduced levels, except in the nuclear affected zones of Bikini and Eniwetok, as prescribed by these laws. Food assistance for Palau will continue at normal levels until a compact is in effect for that area.

Eligibility and Benefits. Household eligibility for FDPIR is determined by income and resources in a manner similar to that used for Food Stamp Program eligibility. Recipients must reside on or near a participating reservation, or reside within a stipulated service area in Oklahoma. In areas where both FDPIR and Food Stamps are available, no household may participate simultaneously in both programs, although they may switch from one program to the other. The entitlement commodities made available to the distributing agencies include canned meats and fish, fruits, vegetables and juice, flour, rice, pasta, cornmeal, dairy products, honey, cereal, oil and shortening. To the extent that surplus price-support commodities are available and can be used without waste, the Commodity Credit Corporation (CCC) donates them for use in this program.

State/Federal Responsibilities. The FDPIR is operated through a partnership between State distributing agencies or Indian Tribal Organizations and the Food and Nutrition Service. The grantee agency is responsible for certifying recipient eligibility, local warehousing and transportation of commodities, distribution of commodities to recipient households, and program integrity.

The Federal Government pays 100 percent of the cost of commodities distributed through the program. In addition, cash payments are made to administering agencies to assist them in meeting the administrative expenses incurred in operating a food distribution program. In Fiscal Year 1994, the Federal Government expects to pay about 80 percent of distributing agencies' administrative expenses. Included among these costs are local warehousing and transportation of commodities, utilities, salaries and equipment.

NUTRITION PROGRAM FOR THE ELDERLY

Overview of Program Development. Food assistance for the Nutrition Program for the Elderly is authorized by Titles III and VI of the Older Americans Act of 1965 (OAA). The Older Americans Act Amendments of 1987 (P.L. 100-175) reauthorized the program through Fiscal Year 1991. The program was most recently reauthorized through Fiscal Year 1995 on September 30, 1992 by P.L. 102-375. The cash and commodities provided are used in preparing meals which are served in senior citizen centers and similar settings or delivered to the home-bound elderly. These meals are the focal point of the nutrition projects for the elderly which have the dual objectives of promoting better health and reducing the isolation of old age.

The Nutrition Program for the Elderly is administered by the U.S. Department of Health and Human Services (DHHS). USDA supplements DHHS programs for the elderly with commodities and/or cash in lieu of commodities for meals served under the provisions of Title III, section 31(a), Grants for State and Community Programs on Aging, and Title VI, Grants for Indian Tribes, of the OAA, as amended.

Eligibility and Benefits. Commodities or cash in lieu of commodities are distributed through State agencies to the local meal sites at a specific rate per meal set by law. P.L. 102-375 established an indexed meal reimbursement rate based on the Consumer Price Index. The legislatively stipulated rate is 63.21 cents per meal for Fiscal Year 1994. However, actual reimbursement for meals served is limited by the appropriation level set by Congress. Most States elect to take all of their subsidies in cash, and some States choose to receive a combination of cash and commodities. The commodities made available to the Nutrition Program for the Elderly are generally the same as those provided to schools under the Child Nutrition Programs. In addition to the per meal reimbursement, States or Indian tribes which elect 20 percent of their benefits in commodities are eligible to receive such bonus commodities as USDA can make available.

Although originally a program to distribute nutritious USDA purchased commodities to senior citizen meal sites, the program has evolved primarily into a cash subsidy program. Approximately 94 percent of program resources are distributed to meal providers in cash.

State/Federal Responsibilities. State Agencies on Aging designate area Agencies on Aging to plan and coordinate the program through local outlets. The State Agencies on Aging and Indian Tribal agencies request USDA-donated foods, cash in lieu of foods, or a combination of both to use in providing meals to the elderly at various sites.

State Agencies on Aging and Indian Tribal Organizations that receive commodities obtain them primarily from the State distributing agency that provides USDA foods to schools for the National School Lunch Program.

COMMODITY PURCHASES FOR SOUP KITCHENS

Overview of Program Development. USDA continues to provide surplus commodities to soup kitchens and food banks as it has in the past. Section 110 of the Hunger Prevention Act of 1988 mandated the purchase and distribution of commodities to soup kitchens and food banks in Fiscal Years 1989 through 1991. In addition, the FACT Act, P.L. 101-624 authorizes appropriations of \$40 million for Fiscal Years 1992-1995 for this purpose.

Eligibility. Commodities are distributed to the States, which, in turn provide them to public and private nonprofit charitable institutions that maintain an established feeding operation to provide food to needy homeless persons and to provide food to needy homeless persons and to food banks which serve such institutions. In instances when the States' full commodity allocation cannot be used by these organizations, States provide such commodities to food banks for distribution to needy households and to organizations that serve meals to predominantly needy persons.

Benefit. USDA provides commodities to States for local distribution to soup kitchens and food banks. USDA anticipates the purchase in Fiscal Year 1994 of the following commodities for these outlets: nonfat dry milk, dehydrated potatoes, and the following canned foods: orange juice, corn, peaches, green beans, fruit cocktail, pineapple, tomatoes, tuna, and pork and/or beef.

State/Federal Responsibilities. Within the States, distribution to soup kitchens and food banks and payments for storage and distribution are the responsibility of State Distributing Agencies. States are responsible for requesting commodities only in quantities that can be efficiently utilized by soup kitchens and food banks and managing the distribution of commodities to local organizations. States are also responsible for ensuring that soup kitchens and food banks comply with all Federal program regulations and requirements.

JUSTIFICATION OF INCREASES AND DECREASES

- (1) A decrease of \$30,187,000 in the appropriation for the Food Distribution Program on Indian Reservations, American Samoa and the Pacific Islands (\$68,641,000 available for Fiscal Year 1994). On the basis of available funds, there is an increase of \$26,078,168 (\$43,538,832 available in 1994).

- (a) A decrease of \$34,229,000 in the appropriation for commodities in lieu of food stamps (\$47,036,000 appropriated in Fiscal Year 1994).

Need for Change. A net decrease in the appropriation consists of:

- A decrease of \$33,229,000 in commodity purchases;
- A decrease of \$1,000 in commodity administrative costs.

Due to lower than expected participation in prior years, federal and grantee inventories have increased.

Nature of Change. The requested funds along with unspent funds from Fiscal Year 1994 will be sufficient to cover about the same level of participation in the Food Distribution Program on Indian Reservations as currently expected in Fiscal Year 1994.

- (b) An increase of \$1,442,000 in the appropriation for distributing agencies' administrative expenses and Nutrition Education (\$18,905,000 available for Fiscal Year 1994).

Need for Change. The funding level for distributing agencies' administrative expenses is based on the cost of prior year operations, including an adjustment for inflation. An estimate of \$1.0 million is included for nationwide expansion of the nutrition education initiative in which Indian Tribal organizations hire and train nutrition aides to provide nutrition education for FDIPIR participants.

Nature of Change. An appropriation of \$20,347,000 will be needed for administrative expenses in Fiscal Year 1995.

- (c) An increase of \$2,600,000 in the appropriation for American Samoa (\$2,700,000 available in Fiscal Year 1994).

Need for Change. An increase of \$2,600,000 will be needed to fully fund annual program operations.

Nature of Change. An appropriation of \$5,300,000 will allow program operations to be fully funded.

- (2) A decrease of \$8,858,000 in the appropriation for the Nutrition Program for the Elderly (\$150,000,000 appropriated for Fiscal Year 1994).

Need for Change. The decrease of \$8,858,000 from the 1994 appropriation to the 1995 request would allow for a rate per meal (cents) of \$57.78. Participation would remain at the 1994 level.

Need for Change. An appropriation of \$141,142,000 will be needed to support this anticipated decrease.

- (3) An increase of \$10,000,000 in the appropriation for Commodities for Soup Kitchens (\$40,000,000 appropriated for Fiscal Year 1994).

Need for Change. This increase will fund commodity purchases for soup kitchens and food banks to help offset the decrease in other commodities available for donation.

Nature of Change. An appropriation of \$50,000,000 will be needed for Soup Kitchens in Fiscal Year 1995.

31-60

Food Distribution Program on Indian Reservations
Program Performance Data

<u>Indian Reservations</u>	<u>FY 1993</u> <u>Actual</u>	<u>FY 1994</u> <u>Estimate</u>	<u>FY 1995</u> <u>Estimate</u>	<u>Change</u>
Average monthly participation 1/	112,399	112,399	112,399	—
Average monthly food package:				
FNS purchased.....	\$33.22	\$34.82	\$37.12	+\$2.30
CCC bonus commodities.....	.60	.61	.63	+.02
Total Monthly Food Package.....	\$33.82	\$35.43	\$37.75	+\$2.32
Annual value of monthly distributions (less bonus).....	\$44,806,737	\$46,964,798	\$50,067,011	+\$3,102,213
Inventory Change	+3,129,265	-26,732,966	-7,814,011	+18,918,955
Subtotal, Commodity Purchases...	47,936,002	20,231,832	42,253,000	+22,021,168
Indian Administration Cost.....	18,143,348	18,905,000	20,347,000	+1,442,000
Disaster Assistance.....	70,668	500,000	500,000	—
Pacific Islands 2/.....	1,018,000	1,027,000	1,043,000	+16,000
American Samoa.....	—	2,700,000	5,300,000	+2,600,000
Commodity Administrative Cost and PCIMS.....	618,933	175,000	174,000	-1,000
Subtotal, Program Level.....	67,786,951	43,538,832	69,617,000	+26,078,168
Funds Available, Start of Year 3/	—	-6,060,832	-31,163,000	-25,102,168
Subtotal, BA Needed.....	67,786,951	37,478,000	38,454,000	+976,000
Funds Available, End of Year.....	6,060,832	31,163,000	—	-31,163,000
Adjustments to NFE Reprogramming.....	-998,445	—	—	—
Total, BA Available.....	72,849,338	68,641,000	38,454,000	-30,187,000
Ending Inventory in Months.....	10.6	4.7	2.6	-2.1

1/ Excludes 4,000 for participation in Palau for all years and participation for American Samoa.

2/ Includes \$581,000 in 1993 through 1995 for the nuclear-affected islands and funds for commodity distribution in Palau.

3/ The \$31.2 million shown as cash resources available for Fiscal Year 1995 will most likely be a combination of cash and a minimum level of inventory. FNS will be working in concert with AMS/ASCS to implement new purchasing practices that will, if successful, permit the operation of the program on a lower inventory level.

Nutrition Program for the Elderly

	<u>FY 1993</u> <u>Actual</u>	<u>FY 1994</u> <u>Estimate</u>	<u>FY 1995</u> <u>Estimate</u>
Meals served (millions)	243	244	244
Rate per meal (cents)	62.06	61.46	57.78

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FOOD DONATIONS PROGRAMS FOR SELECTED GROUPS

STATUS OF PROGRAMS

In Fiscal Year 1993 the Food Donations Programs for Selected Groups continued to provide direct assistance to needy persons through the Food Distribution Program on Indian Reservations (FDPIR), the Needy Family Program, the Nutrition Program for the Elderly (NPE) and Commodities for Soup Kitchens.

Food Distribution Program on Indian Reservations (FDPIR)

The Food Distribution Program on Indian Reservations implements the requirements of Public Law 95-113 and 97-98 to allow Indian Tribal Organizations (ITOs) to operate a food distribution program when they prefer commodities to food coupon and can administer FDPIR. This program is an alternative to the Food Stamp Program for eligible households living on or near an Indian reservation or Indians residing in Oklahoma.

The Administration has identified nutrition education as a high priority objective in the FDPIR. Given the extremely high incidence of diet-related health conditions, such as diabetes, hypertension, and obesity among Native Americans, intensive nutrition education intervention is needed. In the past, these problems have been addressed largely through treatment. The 1988 Surgeon General's Report on Nutrition and Health found that for the two out of three Americans who neither smoke nor drink, eating patterns shape their long term health prospects more than any personal choice. Eating patterns can be shaped or changed by nutrition education that provides appropriate information to help participants make informed and healthful food choices.

In Fiscal Year 1993, the \$135,000 earmarked specifically for nutrition education in FDPIR was made available for FNS regional offices either to purchase nutrition education publications and materials for ITOs and State agencies, or to provide competitive grants to ITOs. The grants have stimulated innovation and are supporting a wide variety of culturally relevant approaches to nutrition education. This money supported 17 various nutrition education projects.

Additionally, a series of 12 nutrition and lifestyle fact sheets covering important aspects of nutrition and health were distributed to households participating in the program in Fiscal Year 1993. These address diet-related health conditions and nutrition issues that are particularly relevant to this population, and they include appropriate recipes that feature foods available through the program.

FNS also took the initiative and formed the Interagency Task Force for Native American Nutrition Education, which is comprised of nine Federal agencies and two national Native American organizations. The goal of the task force is to provide more and better nutrition education for Native Americans served through Federal programs through increased interagency coordination and cooperation. The Federal agencies represented on the task force administer programs dealing with nutrition, health and education for Native Americans. The Native American organizations represent tribal and State administrators of nutrition programs that serve the target population. The identification for nutrition education needs specific to this population group, and the efficient use of human and financial resources to effectively address these needs, are goals of the task force.

At the close of Fiscal Year 1993, 88 ITOs and 6 States operated the FDPIR on 243 Indian reservations. Participation in the FDPIR reached a monthly average of about 112,000 participants. Food valued at approximately \$49.7 million was distributed through FDPIR. In addition, food valued at \$1.4 million was donated to FNS without charge to FDPIR from section 32 surplus removal and section 416 price support activities to meet basic food needs.

Purchases for the Commodity Supplemental Food Program (CSFP) and the Food Distribution Program on Indian Reservations (FDPIR) were reduced in Fiscal Year 1993. Some direct shipments were not purchased, but were filled from storage to reduce excessive inventories. The excessive inventories were caused by inventory identification problems due to conversion data from PCI to PCIMS, declining participation in the programs, and the additional inventory of reconditioned product from the Americold Fire. Excess Fiscal Year 1993 funds may be carried over for use in Fiscal Year 1994 after the reconciliation is completed.

Needy Family Program

The Needy Family Program provided commodities for distribution to eligible households living in Palau. A cash grant for the administrative costs associated with the distribution of commodities was also provided.

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Pursuant to P.L. 99-239, P.L. 99-658, and their Compacts of Free Association, the program was phased out for the Marshall Islands and the Federated States of Micronesia during a three year transition period ending in Fiscal Year 1989.

Certain islands in nuclear-affected zones will continue to receive USDA commodities and administrative funds through Fiscal Year 1997, as authorized by P.L. 102-247, enacted February 24, 1992. To continue this program into the current fiscal year \$581,000 was appropriated. The former Trust Territories that ratified the Compact of Free Association continue to be eligible for emergency assistance from the Department for a 15-year period after implementation of the Compact pursuant to the Disaster Relief Act. Until the Compact of Free Association for Palau is implemented, Palau continues to receive assistance under normal program rules.

Disaster Feeding Program for Major Disasters

The Federal Emergency Management Agency is generally responsible for coordinating disaster assistance under the Disaster Relief and Emergency Assistance Act. The Act specifically assigns certain responsibilities relating to disaster food assistance to the Secretary of Agriculture. Other duties have been assigned to the Secretary by Executive Order. These responsibilities include using, pursuant to the authority of the Act, funds appropriated under section 32 to purchase food commodities for assistance in major disasters or emergencies when other food supplies are not readily available. Food assistance requests under section 32 for disasters in Fiscal Year 1993 totalled \$5 million for victims of the Midwest Floods of 1993 which affected 9 states. In addition to funds available from section 32 for presidentially declared disasters, \$0.5 million is also appropriated to this allowance for discretionary use in smaller emergencies.

Nutrition Program for the Elderly (NPE)

The United States Department of Agriculture supplements the Department of Health and Human Services (DHHS) programs for the elderly with cash and commodities for meals served under the provisions of Title III (Grants for State and Community Programs on Aging) and Title VI (Grants for Indian Tribes) of the Older Americans Act of 1965 (OAA), as amended. DHHS funding for NPE totals about three times the size of the USDA program.

These DHHS programs provide elderly persons with nutritionally sound meals served through meals-on-wheels programs or in senior citizen centers and similar settings where the elderly participate in social and rehabilitative activities. These meals often provide the focal point for activities which have the dual objectives of promoting better health and reducing the isolation that may occur in old age.

As authorized by the amendments to the Older Americans Act, P.L. 102-375, signed on September 30, 1992, the Department provided reimbursement for over 243 million meals at the rate of 62.06 cents per meal in Fiscal Year 1993. This 62.06 cents rate of reimbursement, higher than originally estimated based on available funds, was achieved via a reprogramming action that transferred \$8.7 million from the FDIPIR to NPE. This reprogramming action was possible because of lower than anticipated food costs and participation in FDIPIR. The State agencies distributed commodities and/or cash to local elderly nutrition centers. The commodities made available to the Nutrition Program for the Elderly (NPE) were similar in variety to those provided to schools under the Child Nutrition Programs. From the total funding provided in 1993, \$8.1 million was made in the form of commodities and \$142.6 million was cash reimbursement. In addition \$0.8 million was provided, as bonus, without charge to the NPE account from section 32 surplus removal and section 416 price support activities. The balance of FNS's Fiscal Year 1993 appropriated funds for NPE will be made available based on final meal counts due to FNS by December 30, 1993.

Soup Kitchens/Food Banks

Pursuant to the Hunger Prevention Act of 1988, Public Law 100-435, \$32 million was appropriated in Fiscal Year 1993 to purchase, process, and distribute commodities to soup kitchens and food banks, with priority given to institutions which prepare meals for the homeless.

Commodities were allocated to the States based on a formula which considers the unemployment rate in each State and the number of persons in each State with incomes below the poverty level, as compared to nationwide figures.

In Fiscal Year 1993, approximately 58.0 million pounds of commodities valued at the full \$32 million appropriation were purchased and made available to States for distribution to soup kitchens and food banks. The commodities that were made available were frozen chicken, turkey roast, and beef; nonfat dry milk; and the following canned foods: applesauce, fruit cocktail, pears, pineapple, corn, green beans, peas, tomato juice, chicken and pork.

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**FOOD DISTRIBUTION PROGRAM ON INDIAN RESERVATIONS
AND THE NEEDY FAMILY PROGRAM**

**PARTICIPATION AND FUNDING
FISCAL YEAR 1993**

STATE OR TERRITORY	AVERAGE MONTHLY PARTICIPATION	FOOD COSTS	ADMINISTRATIVE FUNDING
Arizona	19,859	\$7,997,560	\$1,891,255
California	5,157	2,099,341	733,165
Colorado	491	164,840	113,071
Florida	326	101,612	67,146
Idaho	1,745	648,025	208,036
Iowa	65	23,152	32,410
Kansas	445	165,460	120,331
Michigan	1,783	722,663	347,626
Minnesota	3,661	1,430,550	700,466
Mississippi	627	203,579	81,426
Montana	5,282	2,109,884	1,414,769
Nebraska	1,808	671,782	231,185
Nevada	1,423	552,081	170,647
New Mexico	7,184	2,324,687	859,258
New York	686	211,949	147,147
North Carolina	609	255,938	75,693
North Dakota	5,458	2,161,840	843,193
Oklahoma	32,346	13,389,950	3,195,273
Oregon	1,588	636,928	261,639
South Dakota	11,529	4,724,543	1,999,098
Utah	413	124,118	82,553
Washington	4,242	1,616,842	653,043
Wisconsin	3,652	1,353,512	670,214
Wyoming	1,440	553,391	250,191
American Samoa	0	0	0
Freely Associated States	3,980	20,808	0
ARS/ADCS PCINE Admin Expenses	0	618,933	0
Undistributed	0	4,759,635	2,994,513
TOTAL	115,799	\$49,643,603	\$18,143,348

1/ Includes values for entitlement foods but not for bonus commodities.

NOTE: These data are based in part on preliminary data submitted by State and local agencies and are subject to change as revised reports are received.

FOOD DISTRIBUTION PROGRAM ON INDIAN RESERVATIONS AND FOR DISASTER FEEDING
Quantity and Value of Commodities

By Commodity, Fiscal Year 1993

Page 1 of 2

ENTITLEMENT COMMODITIES	Indian Reservations		Disaster Feeding	
	Pounds	Dollars	Pounds	Dollars
SECTION 6/32 TYPE:				
APPLE JUICE, CANNED	2,483,577	\$710,200	46,163	\$12,423
APPLES, FRESH	0	0	116	29
APPLESAUCE, CANNED	884,616	318,850	242,523	85,961
BEANS, DRY	2,244,552	620,888	41,280	13,248
BEANS, GREEN, CANNED	1,568,172	437,422	201,326	57,872
BEANS, CND PINTO	0	0	284	65
BEANS, VEGETARIAN	1,854,888	465,726	240	58
BEEF, CANNED W/HJ	1,253,420	1,887,502	175,436	272,753
BEEF, FROZEN W/ROUND	39,600	63,833	3,744	4,604
CARROTS	822,000	248,382	54,960	16,529
CHICKEN, CANNED BONED	885,483	1,711,587	92,133	181,494
CHICKEN, BREADED	0	0	60	66
CORN, LIQUID	0	0	36,252	15,345
CORN, CREAM STYLE	837,624	290,202	14,160	4,835
CORN, WHOLE KERNEL	1,663,992	571,594	63,144	22,939
EGG MIX	624,582	1,105,625	0	135
EGGS, WHOLE FROZEN	0	0	180	94
FRUIT COCKTAIL, CANNED	2,192,928	1,364,878	31,200	21,060
GRAPE JUICE, CANNED	1,672,798	553,336	32,794	11,203
GRAPEFRUIT JUICE, CANNED	1,080,178	282,823	21,423	5,708
LENTILS	47,304	13,534	0	0
MEAT, LUNCHEON CANNED	1,133,280	1,563,652	144,000	203,717
MEATBALL STEW	996,479	742,269	38,994	27,587
MIXED FRUIT	0	0	181,260	83,552
ORANGE JUICE, CANNED	3,760,706	1,054,596	64,613	21,858
PEACHES, CLING CANNED	3,185,448	1,926,383	449,676	205,487
PEACHES, FREE SLICED	0	0	437	225
PEARS, CANNED	1,748,688	816,120	226,813	92,567
PEAS, DRY SPLIT	0	0	0	0
PEAS, GREEN CANNED	926,448	315,027	47,760	19,070
PINEAPPLE CANNED	1,483,260	786,278	40,380	20,115
PINEAPPLE JUICE	854,227	258,366	16,777	5,244
PLUMS, CANNED, PURPLE	664,296	258,480	0	0
PORK, CANNED W/HJ	963,660	1,348,708	94,395	123,613
PORK FRZ GROUND	0	0	72	77
POTATOES, DEHYDRATED	928,092	488,442	5,568	3,007
POTATOES, FRZ ROUNDS	0	0	60	17
POTATOES, OVEN FRY	0	0	0	0
POTATOES, WHOLE	765,600	227,812	49,152	14,320
PRUNES, DRIED	648,120	598,609	0	0
PUMPKIN	77,424	26,819	0	0
RAISINS	1,047,984	615,701	6,000	3,492
SALMON, PINK CANNED	798,612	1,250,123	38,145	62,270
SPINACH, CANNED	435,332	146,267	2,250	739
SWEET POTATOES, SYRUP	499,848	186,075	104,640	40,193
SYRUP, CORN	637,324	199,353	0	0
TOMATO JUICE, CANNED	950,423	194,255	21,207	4,687
TOMATO PASTE, CANNED	0	0	42	16
TOMATO SAUCE	998,306	286,109	12,783	3,693
TOMATOES CANNED	1,166,112	404,927	20,697	9,465
TURKEY GROUND	0	0	40,000	21,276
TURKEY, ROASTS FRZ	0	0	80,000	107,331
TUNA, CHUNK LIGHT-WATER	901,914	1,174,815	10,313	12,125
Total Section 6/32 Type	45,727,297	\$25,516,145	2,753,554	\$1,812,172
SECTION 416-TYPE:				
CEREAL, DRY CORN	550,016	\$616,722	0	\$0
CEREAL, DRY OATS	274,179	392,766	0	0
CEREAL, DRY RICE	300,516	336,193	90,685	101,676
CEREAL, DRY WHEAT	67,044	92,303	0	0
CEREAL, INFANT RICE	0	0	0	0
CEREAL, INSTANT OATMEAL ENR	0	0	0	0
CEREAL, WHEAT	0	0	0	0
CHEESE, PROCESS	2,863,710	3,918,618	0	0
CHEESE, MOZZARELLA	0	0	0	0
CORNMEAL	80,050	56,353	0	0
FARINA	489,867	194,239	0	0
FLOUR	6,985,450	955,250	0	0
FLOUR MIX	1,605,930	710,835	0	0
FORMULA, INFANT	0	0	0	0
HONEY	20,664	13,303	0	0
MACARONI	1,584,120	424,360	0	0
MILK, EVAPORATED	7,648,760	3,520,226	0	0
MILK, WFD	2,017,224	2,233,475	0	0
OATS, ROLLED	1,572,876	366,451	0	0
OIL, VEGETABLE	658,337	296,638	0	0
PEANUT BUTTER	1,312,128	1,098,915	0	0
PEANUTS, ROASTED	712,926	787,375	0	0
RICE, BROWN	0	0	0	0
RICE, MILLED	2,379,456	477,825	0	0
SHORTENING, VEGETABLE	934,308	383,287	0	0
SPAGHETTI, ENRICHED	1,300,704	383,812	0	0
WHEAT, ROLLED	71,856	22,426	0	0
Total Section 416-Type	33,430,121	\$17,261,372	90,685	\$101,676
Undistributed		6,267,153		
ANS/ASCS/PCIMS Admin. Expenses		618,933		
Total Commodity Entitlement	79,157,418	\$49,643,603	2,844,239	\$1,913,848

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FOOD DISTRIBUTION PROGRAM ON INDIAN RESERVATIONS AND FOR DISASTER FEEDING
Quantity and Value of Commodities

By Commodity, Fiscal Year 1993

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BONUS COMMODITIES	Indian Reservations		Disaster Feeding	
	Pounds	Dollars	Pounds	Dollars
SECTION 32-TYPE:				
GRAPE JUICE	0	0	152	\$51
PEACHES, FRZ	0	0	120	80
TOMATOES, CRUSHED	0	0	159	48
Total Section 32 Type	0	\$0	431	\$179
SECTION 416-TYPE:				
BUTTER	699,084	\$672,281	115,308	\$112,388
CORNMEAL	1,465,750	641,694	129,600	15,450
WONET	306,108	78,634	0	0
Total Section 416 Type	2,470,942	\$1,392,609	244,908	\$127,838
Total Bonus Commodities	2,470,942	\$1,392,609	245,339	\$128,017
GRAND TOTAL (Entitlement & Bonus)	\$1,628,360	\$51,036,212	3,089,578	\$2,041,865

SOURCE: Preliminary food orders for fiscal year 1993.

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NUTRITION PROGRAM FOR THE ELDERLY
MEALS SERVED AND PROGRAM COSTS

FISCAL YEAR 1993

STATE OR TERRITORY	MEALS SERVED		FNS PROGRAM COSTS a/
	AVERAGE DAILY	TOTAL FY 1993	
Alabama	14,256	3,763,496	\$2,295,731
Alaska	2,044	539,530	329,113
Arizona	10,451	2,759,060	1,683,027
Arkansas	15,567	4,104,354	2,503,656
California	72,345	19,098,992	11,650,385
Colorado	8,030	2,122,319	1,294,615
Connecticut	10,350	2,732,342	1,666,729
Delaware	3,478	918,268	560,143
District of Columbia	5,222	1,378,590	840,940
Florida	40,986	10,820,700	6,600,322
Georgia	13,995	3,694,588	2,253,699
Hawaii	3,805	1,004,481	612,733
Idaho	1,127	1,353,642	825,722
Illinois	32,645	8,618,302	5,257,164
Indiana	16,073	4,243,266	2,588,392
Iowa	16,661	4,398,404	2,683,026
Kansas	15,460	4,081,464	2,489,693
Kentucky	13,205	3,486,121	2,126,534
Louisiana	19,289	5,092,219	3,106,254
Maine	4,399	1,161,220	708,344
Maryland	15,690	4,142,132	2,526,701
Massachusetts	26,327	6,950,770	4,219,665
Michigan	37,851	9,992,659	6,095,522
Minnesota	19,282	5,090,471	3,105,187
Mississippi	11,499	3,035,713	1,851,785
Missouri	23,846	6,295,435	3,860,215
Montana	7,619	2,011,477	1,227,001
Nebraska	9,371	2,474,069	1,509,182
Nevada	4,605	1,215,612	741,523
New Hampshire	4,905	1,295,025	789,965
New Jersey	21,602	5,702,809	3,478,713
New Mexico	10,405	2,746,934	1,675,630
New York	90,896	23,996,414	14,637,813
North Carolina	19,072	5,034,906	3,071,295
North Dakota	6,139	1,620,722	988,640
Ohio	31,217	8,241,266	5,027,172
Oklahoma	18,873	4,982,467	3,039,305
Oregon	10,769	2,863,020	1,734,242
Pennsylvania	45,044	11,891,670	7,253,919
Rhode Island	4,616	1,218,524	743,300
South Carolina	8,904	2,350,467	1,433,907
South Dakota	7,027	1,855,117	1,131,621
Tennessee	13,811	3,644,132	2,224,141
Texas	63,565	16,781,058	10,236,445
Utah	6,192	1,634,615	997,115
Vermont	3,133	826,966	504,461
Virginia	12,802	3,400,919	2,074,561
Washington	13,218	3,489,620	2,128,668
West Virginia	9,480	2,502,809	1,526,713
Wisconsin	22,040	5,818,626	3,549,362
Wyoming	4,651	1,227,983	749,070
American Samoa	0	0	0
Guam	1,327	350,259	213,658
North Mariana Island	397	104,737	63,890
Puerto Rico	10,284	2,714,851	1,656,059
Trust Territory (excluding NH)	0	0	0
Virgin Islands	0	0	0
Indian Tribe Set Asi	0	0	0
Indian Tribes	0	0	0
Freely Associated States	0	0	0
AHS/ASCS/PCIMS Admin Exp	0	0	74,000
Anticipated Adjustment	0	0	2,448,551
TOTAL	919,916	242,856,830	\$150,665,217

a/ Meals served times rate. Rate is \$62.06 per meal.

NOTE: Data for Title III and VI Programs are based in part on preliminary data submitted by the States and local agencies and are subject to change as revised reports are received. Totals may not add due to rounding.

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NUTRITION PROGRAM FOR THE ELDERLY
Quantity and Value of Commodities

School or Fiscal Year 1993

Page 1 of 2

ENTITLEMENT COMMODITIES	Pounds	Dollars
SECTION 6/32 TYPE:		
APPLE SLICES, CANNED	132,873	\$54,018
APPLES, FRESH	38,192	9,600
APPLESAUCE, CANNED	321,288	91,647
BEANS, GREEN, CANNED	351,500	100,103
BEANS, GREEN, FROZEN	201,000	69,037
BEANS, REFRIED, CANNED	672	205
BEEF PATTIES, FRZ	15,264	21,178
BEEF, FROZEN GROUND	929,880	1,169,843
BLACKBERRIES FRZ	41,070	31,390
BLUEBERRIES	85,620	70,634
CHERRIES FRZ	19,200	7,893
CHICKENS, DICED FRZ.	134,120	305,590
CHICKENS, FROZEN, CUT-UP	604,080	381,836
CORN, CANNED, LIQUID	223,080	67,980
CORN CANNED VACUUM	1,293	629
CORN FROZEN	124,830	45,546
EGGS, WHOLE FROZEN	67,020	29,402
MIXED FRUIT	356,958	180,389
PEACHES, CLING CANNED	763,678	362,390
PEACHES, FREESTONE FRZ SLICED	3,220	2,044
PEARS, D'ANJOU FRESH	40,500	12,276
PEARS, DICED	149,153	58,435
PEARS, HALVES	118,856	46,970
PEARS, SLICED	161,555	63,365
PEAS, GREEN CANNED	95,393	24,266
PEAS, GREEN FROZEN	210,030	74,259
PINEAPPLE, CANNED	363,674	192,737
PLUMS, CANNED PITTED	111,459	41,915
PORK, FRZ GROUND	86,580	88,201
POTATO ROUNDS, FROZEN	175,170	50,087
POTATOES, OVEN FRY	42,480	11,905
RAISINS	1,500	769
SWEET POTATOES, SYRUP	128,953	52,579
SALSA	557	198
TUNA	42,120	45,916
TURKEY ROASTS, FROZEN	508,880	699,588
TURKEY, FROZEN GROUND	277,840	167,618
TURKEY, FROZEN WHOLE	167,600	101,836
Total Section 6/32 Type	7,097,138	\$4,734,276

continued on the next page

NUTRITION PROGRAM FOR THE ELDERLY
Quantity and Value of Commodities

School or Fiscal Year 1993

Page 2 of 2

ENTITLEMENT COMMODITIES	Thousands of Pounds	Thousands of Dollars
SECTION 416-TYPE:		
CHEESE, CHEDDAR	80,370	\$90,859
CHEESE, MOZZARELLA	6,288	8,465
CHEESE, PROCESS	300	403
FLOUR	233,000	29,337
MACARONI	94,500	22,924
OIL, VEGETABLE	15,293	5,242
PEANUT BUTTER	38,611	29,492
PEANUT, ROASTED	720	756
RICE, MILLED	66,775	11,706
ROTIINI	6,700	1,925
SHORTENING, VEGETABLE	5,868	2,470
SPAGHETTI, ENRICHED	58,380	16,868
Total Section 416-Type	604,805	\$218,537
Anticipated Adjustment		3,047,187
ARS/ASCS/PCIS Admin. Expenses		74,000
Total Commodity Entitlement	7,701,943	\$8,074,000
BONUS COMMODITIES		
SECTION 32-TYPE:		
ALMOND SLIVERS		
ASPARAGUS, CANNED	33,744	\$27,027
ASPARAGUS FROZEN	42,600	56,090
BEANS, DRY PINTO	10,725	2,712
BEANS, CND PINTO	21,425	\$4,493
BEANS, REFRIED	38,304	12,082
BEANS, VEGETARIAN	55,809	\$11,929
BLACKBERRY PUREE	60,858	41,402
CHERRIES FRZ	61,740	26,567
CHICKEN CUT UP	10,000	5,757
CHICKENS, FRZ DRUM	8,000	2,810
CHICKENS, FRZ LEGS	7,440	2,419
CHICKEN THIGHS	1,600	504
DATE PIECES	43,050	33,732
GRAPE JUICE	137,902	46,640
ORANGE JUICE FRZ CONC	132,000	67,287
ORANGES FRESH	2,555	450
PEACHES FRZ	34,000	22,593
PEARS SLICED	83,504	34,459
POTATOES, FLAKED DEHYDRATED	108,960	\$56,699
POTATOES, GRANULES	36,000	17,948
SALMON, PINK CANNED	17,523	\$28,950
TOMATOES, CRUSHED	72,624	\$21,910
TOMATO PASTE, CANNED	2,140	\$786
TOMATO SAUCE	20,352	5,234
TOMATOES, CANNED	12,240	\$4,045
Total Section 32 Type	1,055,095	\$534,815
SECTION 416-TYPE:		
BUTTER	289,908	\$260,690
CORNMEAL	21,600	2,403
FLOUR		
Total Section 416 Type	311,508	\$263,093
Total Bonus Commodities	1,366,603	\$797,908
TOTAL - ALL COMMODITIES	9,068,546	\$8,871,908
CASH IN LIEU OF COMMODITIES		142,591,217
GRAND TOTAL	9,068,546	\$151,463,125

Source: Preliminary food orders for school or fiscal year 1993.

Note: Due to rounding, the individual entries may not add to the totals shown.

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SOUP KITCHENS AND FOOD BANKS
Quantity and Value of Commodities

By Commodity, Fiscal Year 1993

ENTITLEMENT COMMODITIES	Pounds	Dollars
SECTION 6/32 TYPE:		
APPLESAUCE, CANNED	3,009,600	\$1,102,523
BEANS, GREEN CANNED	7,569,315	2,269,969
BEANS, VEGETARIAN	36,720	9,571
BEEF GROUND	435,600	538,021
CHICKEN, CANNED BOWED	3,178,980	6,250,235
CHICKEN, FRZ CUT-UP	1,000,000	633,250
CORN, WHOLE KERNEL	3,009,600	1,169,583
FRUIT COCKTAIL	4,890,600	3,085,467
PEARS, CANNED	1,539,000	798,593
PEAS, GREEN CANNED	5,882,400	1,779,426
PINEAPPLE CANNED	5,322,240	2,629,187
PORK, CANNED, W-WJ	3,401,439	4,316,255
POTATOES, DEHYDRATED	330,000	228,103
POULTRY, CANNED BOWED	0	0
TOMATO JUICE	14,937,552	3,412,604
TURKEY ROASTS	160,000	223,660
Total Section 6/32 Type	54,703,046	\$28,446,447
SECTION 416-TYPE:		
NFD MILK	2,534,400	\$3,160,170
RICE, MILLED	714,000	130,383
Total Section 416 Type	3,248,400	\$3,290,553
Anticipated Adjustment		0
AMS/ASCS/PCIMS Admin. Expenses		263,000
Total Commodity Entitlement	57,951,446	\$32,000,000

SOURCE: Preliminary final food orders for fiscal year 1993.

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SURPLUS COMMODITY DONATIONS TO
CHARITABLE INSTITUTIONS AND SUMMER CAMPS

STATUS OF PROGRAM

Under section 416 price support and section 32 surplus removal authorities, commodities are acquired by the Commodity Credit Corporation (CCC) and the Agricultural Marketing Service (AMS) and are made available at no cost to the Surplus Commodity Donations Program administered by FNS.

Commodities are distributed to nonprofit charitable institutions serving needy persons and to summer camps for children. To be eligible, an institution must be nonprofit and serve meals on a regular basis. Among the charitable institutions receiving donated commodities are: homes for the elderly, hospitals that offer general and long term health care, soup kitchens, meals-on-wheels programs and orphanages that do not participate in any of the Child Nutrition Programs. Similar rules apply to both institutions and summer camps. Those camps participating in the Summer Food Service Program are not eligible to receive commodities through this program. The Charitable Institutions and Summer Camp Program is one of FNS' largest outlets for commodities bought under farm program authorities and can absorb products during the summer when schools, the largest outlet, cannot.

In Fiscal Year 1993, foods valued at \$95.4 million were distributed to charitable institutions. An additional \$3.5 million in food was distributed to summer camps.

31g-53

SUMMER CAMPS AND CHARITABLE INSTITUTIONS
Quantity and Value of Commodities

By Commodity, Fiscal Year 1993

ENTITLEMENT COMMODITIES	Summer Camps		Charitable Institutions	
	Pounds	Dollars	Pounds	Dollars
SECTION 6/32 TYPE:				
MEAT, LUNCHEON CANNED	0	\$0	0	\$0
PORK, CANNED W/HJ	0	\$0	0	0
Total Section 6/32 Type	0	\$0	0	\$0
SECTION 416-TYPE:				
CORNMEAL	92,650	\$10,463	6,357,050	\$716,190
FLOUR	15,000	2,256	0	0
GRITS, CORN	15,350	2,246	2,393,150	309,537
MACARONI	547,260	133,298	9,711,080	2,411,947
OATS, ROLLED	291,732	56,946	6,722,408	1,274,636
OIL, SALAD DRESSING SOC	0	0	58,822	19,340
OIL, VEGETABLE	1,265,548	436,686	30,980,601	10,254,030
PEANUT BUTTER	882,928	663,986	14,072,014	10,876,859
PEANUT GRANULES	24,066	21,820	335,727	347,483
PEANUTS, ROASTED	268,704	257,845	4,240,504	4,169,352
RICE, BROWN	0	0	252,000	38,900
RICE, MILLED	508,600	83,508	17,482,386	3,003,972
ROTIMI	629,320	185,002	5,148,000	1,441,053
SHORTENING, LIQUID VEG	111,527	40,360	5,139,547	1,842,278
SHORTENING, VEGETABLE	704,133	293,488	17,737,266	7,113,567
SPAGHETTI, ENRICHED	444,400	112,982	8,824,845	2,271,476
WHEAT, ROLLED	0	0	1,386,000	219,158
Total Section 416-Type	5,801,218	\$2,300,886	130,841,400	\$46,309,778
Total Commodity Entitlement	5,801,218	\$2,300,886	130,841,400	\$46,309,778
BONUS COMMODITIES				
SECTION 32-TYPE:				
CHERRIES FRZ	40,650	\$18,639	5,164,610	\$2,306,838
GRAPFRUIT FRESH			874,505	202,544
ORANGES	45,554	8,027	2,192,818	386,401
ORANGE JUICE FRZ			1,570,170	800,388
PEACHES CND	387,762	176,095	2,691,924	345,937
PEARS DICED	118,224	50,026	1,064,706	452,153
PEARS HALVES	15,800	8,995	409,062	181,097
PEARS SLICED	0	0	599,612	267,204
POTATO BAKING			481,750	78,786
SALMON, PINK CANNED	0	0	2,308,310	3,462,448
TOMATOES, FRESH			464,615	184,990
TOMATO PASTE			828,282	307,922
TOMATO SAUCE	0	0	1,792,732	461,007
TOMATOES, CANNED	0	0	2,467,745	853,916
TOMATOES, CRUSHED	0	0	1,558,800	472,414
Total Section 32 Type	607,990	\$259,782	24,469,701	\$10,764,045
SECTION 416-TYPE:				
BUTTER	1,043,028	944,983	41,414,244	38,268,192
BUTTER PATTIES, SOC	0	0	102,990	81,621
Total Section 416 Type	1,043,028	\$944,983	41,517,234	\$38,349,813
Total Bonus Commodities	1,651,018	\$1,204,765	65,986,935	\$49,113,858
GRAND TOTAL (Entitlement & Bonus)	7,452,236	\$3,505,651	196,828,335	\$95,423,636

SOURCE: Preliminary final food orders for fiscal year 1993

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SUMMER CAMPS AND CHARITABLE INSTITUTIONS
Value of Surplus Commodity Donations

Fiscal Year 1993

State or Territory	Summer Camps	Charitable Institutions	TOTAL
Alabama-----	31,524	1,392,568	\$1,424,092
Alaska-----		284,095	284,095
Arizona-----	42,580	1,615,364	1,657,944
Arkansas-----	17,108	892,359	909,467
California-----	141,995	16,836,594	16,978,589
Colorado-----	62,257	1,266,833	1,329,090
Connecticut-----	62,746	128,639	191,385
Delaware-----	322	449,383	449,705
District of Columbia-----		680,013	680,013
Florida-----	58,833	3,911,464	3,970,297
Georgia-----	77,071	3,081,759	3,158,830
Hawaii-----	4,689	278,953	283,642
Idaho-----	52,717	435,259	487,976
Illinois-----	37,961	336,342	374,303
Indiana-----	58,879	194,684	253,563
Iowa-----	100,774	917,797	1,018,571
Kansas-----		1,096,988	1,096,988
Kentucky-----	12,576	983,905	996,481
Louisiana-----	9,579	2,487,887	2,497,466
Maine-----	72,516	38,582	111,098
Maryland-----	25,798	1,888,014	1,913,812
Massachusetts-----	49,130	2,808,693	2,857,823
Michigan-----	185,965	3,587,091	3,773,056
Minnesota-----	162,669	1,926,885	2,089,554
Mississippi-----	10,222	1,237,472	1,247,694
Missouri-----	42,186	1,907,463	1,949,649
Montana-----	6,396	367,774	374,170
Nebraska-----	12,840	458,579	471,419
Nevada-----	346	536,675	537,021
New Hampshire-----	167,981	439,559	607,540
New Jersey-----	36,519	1,734,963	1,771,482
New Mexico-----	2,371	369,115	371,486
New York-----	589,084	8,807,439	9,396,543
North Carolina-----	54,172	1,820,439	1,874,611
North Dakota-----	30,965	433,771	464,736
Ohio-----		1,843,831	1,843,831
Oklahoma-----	279,395	1,276,807	1,556,202
Oregon-----	105,921	1,164,320	1,270,241
Pennsylvania-----	396,227	4,900,157	5,296,384
Rhode Island-----	63,154	204,247	267,399
South Carolina-----		1,396,019	1,459,173
South Dakota-----	11,512	258,860	270,372
Tennessee-----		1,224,127	1,224,127
Texas-----	64,002	8,751,219	8,815,221
Utah-----	25,356	477,643	502,999
Vermont-----	22,950	376,193	399,143
Virginia-----	89,242	1,182,258	1,271,500
Washington-----	111,884	2,176,392	2,288,276
West Virginia-----	49,891	1,256,503	1,306,394
Wisconsin-----	58,581	2,388,392	2,446,973
Wyoming-----	6,765	208,505	215,270
American Samoa-----			0
Freely Associated States-----			0
Guam-----		1,080	1,080
N. Mariana Islands-----			0
Puerto Rico-----		703,663	703,663
Virgin Islands-----			0
Indian Tribes-----			0
DOD Army/AF/USMC/NAVY-----			0
Undistributed-----			0
TOTAL-----	83,505,651	895,423,636	998,929,287

SOURCE: Preliminary final food orders for fiscal year 1993.

31-61

FOOD AND NUTRITION SERVICE

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

The Emergency Food Assistance Program:

For necessary expenses to carry out the Emergency Food Assistance Act of 1983, as amended, \$40,000,000: Provided, That, in accordance with section 202 of Public Law 98-92, these funds shall be available only if the Secretary determines the existence of excess commodities. [For purchases of commodities to carry out the Emergency Food Assistance Act of 1983, as amended, \$80,000,000]

This change deletes language that provides funds for the procurement of commodities for distribution within The Emergency Food Assistance Program. This change will not affect the continued distribution of bonus commodities.

31-62

THE EMERGENCY FOOD ASSISTANCE PROGRAM

Appropriations Act, 1994	\$120,000,000
Budget Estimate, 1995	<u>40,000,000</u>
Decrease in Appropriation	<u>-80,000,000</u>

SUMMARY OF INCREASES
(On basis of appropriation)

<u>Item of Change</u>	<u>1994</u> <u>Estimated</u>	<u>Program</u> <u>Change</u>	<u>1995</u> <u>Estimated</u>
The Emergency Food Assistance Program			
Total Available	<u>\$120,230,000</u>	<u>-\$80,000,000</u>	<u>\$40,230,000</u>

PROJECT STATEMENT
(On basis of adjusted appropriation)

	1993 Actual Amount	1994 Estimated Amount	Increase or Decrease	1995 Estimated Amount
<u>Project</u>				
Administrative Costs	\$44,987,035	\$40,000,000	\$	\$40,000,000
P.L. 103-66...2/.....	—	10,000	—	10,000
Subtotal, Administrative Costs.....	44,987,035	40,010,000	—	40,010,000
Commodity Procurement	119,999,990	80,000,000	-80,000,000	—
P.L. 103-66...2/.....	—	220,000	—	220,000
Subtotal, Commodity Procurement.....	119,999,990	80,220,000	-80,000,000	220,000
Total, Obligations.....	164,987,025	120,230,000	-80,000,000	40,230,000
Unobligated Balance Expiring.....	12,975	—	—	—
Total Appropriation.....	165,000,000	120,230,000	-80,000,000	40,230,000

1/ Excludes \$42,329,000 in one-time funds provided by P.L. 102-552.

2/ Provides \$230,000 for TEFAP demonstration projects for Fiscal Years 1994 through 1996.

EXPLANATION OF PROGRAM

Overview of Program Development. The Emergency Food Assistance Program (TEFAP) evolved from the Special Dairy Distribution Program which began December 11, 1981, with the release of 30 million pounds of cheese. The program has the dual goal of reducing the government held commodity surpluses and providing emergency food assistance to low-income individuals and households. TEFAP was formally authorized in 1983 by Section 204 of Public Law 98-8 including the provision of funds to State and local agencies to share some of the cost of intrastate distribution of the commodities. Public Law 98-92 appropriated funds for Fiscal Year 1983 and authorized funds through Fiscal Year 1985 for costs of storage and intrastate distribution of Commodity Credit Corporation commodities donated to needy individuals by States. Public Law 100-77 authorized funds through Fiscal Year 1988 for this purpose.

For Fiscal Years 1989 and 1990, the Hunger Prevention Act of 1988 authorized \$50 million for continued support of State administrative activities and \$120 million for the purchase and distribution of additional commodities that were high in nutrient content, as well as safely and easily stored and used. The purchased commodities were in addition to commodities that could be made available from USDA inventories. These activities were reauthorized by the FACT Act of 1990, P.L. 101-624. Specific authorizations for appropriation of funds for commodity purchases were included for Fiscal Years 1991-1995.

Eligibility. Commodities are distributed to the States which, in turn, provide them to low-income and unemployed persons, according to income-based eligibility criteria set by the States. States are allocated commodities based on a formula which considers the number of persons in each State below the poverty level (60 percent) and the number of persons unemployed (40 percent).

Benefits. USDA provides commodities and cash subsidies for State and local expenses incurred for storage and distribution of USDA donated commodities. USDA will distribute surplus butter and cornmeal in Fiscal Year 1994. In addition, funds have been provided by direct appropriation so that USDA may also purchase foods high in nutrient density specifically for distribution via TEFAP. The additional foods USDA plans to purchase in Fiscal Year 1994 include canned peas, green beans, applesauce, orange juice, pork, and beef, as well as peanut butter, raisins, rice, and dry bagged beans.

In Fiscal Year 1994, a total of \$40 million in administrative funds will be distributed by the Food and Nutrition Service (FNS) to States through grants. Allocation of administrative funds to States is based on the same formula used to allocate commodities to States (the number of persons in each State below the poverty level and the number of unemployed persons).

In each of Fiscal Years 1994 through 1996, P.L. 103-66, The Omnibus Budget Reconciliation Act of 1993, has provided \$230,000 in mandatory funds to operate TEFAP demonstration projects in two states. The demonstration projects are designed to test commodities that are low in sodium, fat, sugar and are high in nutrients.

State/Federal Responsibilities. The Emergency Food Assistance Program operates as a Federal/State partnership under agreements entered into between FNS and State agencies. Once the foods are made available to States, the overall organization and administration of the program become the responsibilities of State agencies. Each State is responsible for selecting emergency feeding organizations to distribute the commodities and for determining the eligibility of persons to participate. The frequency of the distributions, as well as the quantities of commodities to be distributed to local areas, are also determined by each State distributing agency.

State administrative costs are subsidized by the Federal government. However, by statute, States must pass down at least 40 percent of their administrative funding to local organizations. State distributing agency costs include contracted services such as warehousing and delivery of commodities.

State distributing agencies coordinate the activities of emergency feeding organizations, which in turn serve distribution sites nationwide. Typical distribution sites include churches and community action agencies; many sites have other principal purposes unrelated to food distribution. They are staffed largely by volunteers.

The Federal government pays 100 percent of the costs of surplus commodities donated to States, plus the cost of purchased commodities, and provides grants of administrative funds. USDA also pays for processing the commodities into household size packages, and shipping them to locations within the States.

JUSTIFICATION OF INCREASES AND DECREASES

A decrease of \$80,000,000 in the appropriation for commodity procurement (\$80,000,000 available in 1994).

Need for Change. Bonus commodities are provided and made available for distribution within TEFAP each year. The original intent of the program was to distribute excess surplus and price support commodities. Other food assistance programs will continue to be available to help recipients, as will USDA bonus commodities and commodities donated through the private sector.

Nature of Change. A decrease of \$80,000,000 would eliminate all discretionary funds available for commodity procurement.

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THE EMERGENCY FOOD ASSISTANCE PROGRAM

STATUS OF PROGRAM

Funds for The Emergency Food Assistance Program (TEFAP) are provided to States to help finance State and local costs associated with the transportation, processing, storage and distribution of donated commodities. A total of \$224.6 million in bonus and purchased commodities were provided for Fiscal Year 1993 for household distribution.

Current Activities

TEFAP commodities and funds for intrastate distribution are allocated to the States based on a formula which considers the unemployment rates in the States and the number of persons in each State with incomes below the poverty level. During Fiscal Year 1993, \$207.3 million was appropriated for commodities and administrative funding. This includes one-time assistance of \$42.3 million for the purchase of commodities, as provided under P.L. 102-552.

Bonus commodities totaling nearly 110.8 million pounds and valued at \$63.3 million were donated to the States during Fiscal Year 1993 by the USDA. These commodities included butter and cornmeal. The additional commodities purchased and donated for household distribution include: raisins, dry bagged beans, rice, dehydrated potatoes, and the following canned foods: applesauce, orange juice, peaches, pears, fruit cocktail, green beans, peas, vegetarian beans, refried beans, pork, peanut butter, tuna, and apple juice. They totaled over 288.7 million pounds and were valued at \$161.3 million. Both donated and purchased commodities are distributed to the needy through the combined efforts of Federal, State, and local governments, private voluntary organizations and volunteer ad hoc efforts.

Once donated foods are made available to States, the overall organization and administration of the program becomes the responsibility of State agencies. Each State is responsible for selecting emergency feeding organizations to distribute the commodities and for determining the eligibility of persons to participate.

Fiscal Year 1993 TEFAP Summary
(millions)

	<u>Dollars</u>	<u>Pounds</u>
State Administrative Expenses	\$45.0	--
Commodities		
Bonus Commodities	\$63.3	110.8
Purchased Commodities	119.0	212.9
Additional Commodity Procurement		
Funds Provided by P.L. 102-552	<u>42.3</u>	<u>75.8</u>
	224.6	399.5
AMS/ASCS Administration and PCIMS	<u>1.0</u>	--
TOTAL	<u>\$270.6</u>	<u>399.5</u>

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THE EMERGENCY FOOD ASSISTANCE PROGRAM
 Bonus and Entitlement Commodity Donations

Fiscal Year 1993

State or Territory	Pounds of Food	Value in Dollars
Alabama-----	8,154,631 :	\$4,443,966
Alaska-----	708,781 :	361,956
Arizona-----	7,327,218 :	3,869,781
Arkansas-----	4,979,804 :	2,619,255
California-----	70,907,115 :	35,895,561
Colorado-----	3,914,565 :	2,288,071
Connecticut-----	3,761,322 :	2,122,831
Delaware-----	875,463 :	515,487
District of Columbia-----	1,213,338 :	690,792
Florida-----	18,791,419 :	10,903,712
Georgia-----	8,932,764 :	4,889,650
Hawaii-----	1,584,569 :	763,308
Idaho-----	2,192,586 :	1,106,628
Illinois-----	18,279,156 :	10,151,707
Indiana-----	7,260,144 :	4,228,943
Iowa-----	3,044,376 :	1,855,260
Kansas-----	3,356,283 :	1,773,939
Kentucky-----	5,957,680 :	3,303,594
Louisiana-----	9,373,847 :	5,191,237
Maine-----	1,896,785 :	1,137,919
Maryland-----	6,111,430 :	3,517,459
Massachusetts-----	8,884,758 :	4,692,684
Michigan-----	14,391,915 :	8,685,520
Minnesota-----	5,054,904 :	3,086,129
Mississippi-----	6,919,920 :	3,591,590
Missouri-----	7,891,610 :	4,047,601
Montana-----	1,155,408 :	754,348
Nebraska-----	1,713,678 :	1,072,988
Nevada-----	1,677,014 :	905,614
New Hampshire-----	1,401,261 :	818,798
New Jersey-----	9,501,379 :	5,697,236
New Mexico-----	3,201,462 :	1,657,597
New York-----	27,169,118 :	15,741,550
North Carolina-----	8,071,395 :	4,180,653
North Dakota-----	903,040 :	509,514
Ohio-----	18,011,973 :	9,534,464
Oklahoma-----	5,190,837 :	2,582,323
Oregon-----	4,718,361 :	2,246,883
Pennsylvania-----	16,823,970 :	9,700,574
Rhode Island-----	934,926 :	542,394
South Carolina-----	5,329,593 :	2,308,887
South Dakota-----	933,417 :	503,079
Tennessee-----	8,149,356 :	4,708,214
Texas-----	33,312,650 :	19,060,498
Utah-----	2,167,464 :	1,194,869
Vermont-----	993,811 :	547,837
Virginia-----	7,305,966 :	4,149,645
Washington-----	7,243,395 :	4,251,285
West Virginia-----	3,982,077 :	2,485,927
Wisconsin-----	5,573,313 :	3,410,520
Wyoming-----	504,233 :	383,343
American Samoa-----	0 :	0
Guam-----	359,412 :	97,826
North Marian Island-----	156,000 :	37,859
Puerto Rico-----	14,401,470 :	6,575,291
Trust Territory (excluding NMI)-----	0 :	0
Virgin Islands-----	382,833 :	437,676
Indian Tribe Set Asi-----	0 :	0
Indian Tribes-----	0 :	0
Freely Associated States-----	0 :	0
DDO Army/AF/USMC/Navy-----	8,214,336 :	5,836,211
AMS/ASCS Admin Expenses-----	-- :	984,000
Anticipated Adjustment-----	-31,735,856 :	-12,998,647
TOTAL-----	399,513,675 :	\$225,653,836

SOURCE: Preliminary final food orders for fiscal year 1993.

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THE EMERGENCY FOOD ASSISTANCE PROGRAM
Administrative Expense Funding

Fiscal Years 1993-1994

State or Territory	Actual 1993	Estimated 1994
Alabama-----	\$869,097	\$784,320
Alaska-----	81,405	70,560
Arizona-----	686,118	589,760
Arkansas-----	511,019	437,160
California-----	5,468,715	5,115,040
Colorado-----	519,215	448,760
Connecticut-----	402,618	370,360
Delaware-----	87,729	71,040
District of Columbia-----	123,120	109,520
Florida-----	2,321,955	2,026,080
Georgia-----	1,135,575	968,560
Hawaii-----	119,295	113,360
Idaho-----	158,615	150,120
Illinois-----	1,994,447	1,791,600
Indiana-----	787,493	685,640
Iowa-----	381,600	332,440
Kansas-----	318,447	318,120
Kentucky-----	752,590	699,360
Louisiana-----	1,074,735	943,600
Maine-----	177,215	178,360
Maryland-----	634,417	568,760
Massachusetts-----	916,385	731,040
Michigan-----	1,715,317	1,453,880
Minnesota-----	571,907	540,200
Mississippi-----	712,710	601,240
Missouri-----	861,892	774,800
Montana-----	148,302	130,520
Nebraska-----	168,100	167,120
Nevada-----	176,359	172,640
New Hampshire-----	141,750	120,360
New Jersey-----	1,139,265	919,040
New Mexico-----	346,770	320,960
New York-----	3,207,572	2,769,920
North Carolina-----	1,071,848	918,080
North Dakota-----	99,945	89,160
Ohio-----	1,804,545	1,547,400
Oklahoma-----	580,644	528,280
Oregon-----	479,880	450,320
Pennsylvania-----	1,875,058	1,672,720
Rhode Island-----	164,025	137,480
South Carolina-----	632,925	602,080
South Dakota-----	107,730	94,880
Tennessee-----	905,036	802,200
Texas-----	3,653,785	3,236,240
Utah-----	227,385	199,920
Vermont-----	82,730	72,200
Virginia-----	906,075	752,280
Washington-----	729,307	721,040
West Virginia-----	437,175	400,680
Wisconsin-----	650,675	599,240
Wyoming-----	64,080	60,160
American Samoa-----	0	0
Guam-----	16,078	14,480
North Mariana Island-----	7,965	7,240
Puerto Rico-----	1,773,225	1,603,360
Trust Territory (excluding NMI)-----	0	0
Virgin Islands-----	18,135	16,320
Indian Tribe Set Asi-----	0	0
Indian Tribes-----	0	0
Freely Associated States-----	0	0
DDO Army/AF/USMC/Navy-----	0	0
Undistributed-----	-12,965	0
TOTAL-----	\$44,987,035	\$40,000,000

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THE EMERGENCY FOOD ASSISTANCE PROGRAM
Quantity and Value of Commodities

By Commodity, Fiscal Year 1993

ENTITLEMENT COMMODITIES	Pounds	Dollars
SECTION 6/32 TYPE:		
APPLE JUICE	24,948,000	\$6,497,770
APPLESAUCE	21,648,600	8,145,272
BEANS, DRY	12,297,600	4,054,630
BEANS, GREEN, CANNED	7,936,110	2,624,879
BEANS, REFRIED	1,138,320	409,000
BEANS, VEGETARIAN	14,614,560	4,229,386
FRUIT COCKTAIL	14,364,000	8,234,306
ORANGE JUICE, CANNED	38,253,600	9,271,523
PEACHES, CLING CMD	12,722,400	6,841,383
PEARS, CANNED	1,710,000	887,325
PEAS, GREEN CANNED	8,208,000	2,241,796
PORK, CANNED W/NJ	33,362,803	42,457,780
POTATOES, FLAKES DEHY	3,360,000	2,322,498
RASINS	20,321,280	12,177,892
TUNA, CANNED	4,895,100	6,916,913
Total Section 6/32 Type	219,780,373	\$117,312,353
ENTITLEMENT COMMODITIES		
SECTION 416-TYPE:		
PEANUT BUTTER	51,798,432	\$40,580,521
RICE MILLED	17,184,240	3,369,657
Total Section 416-Type	68,982,672	\$43,950,178
AMS/ASCS/PCIMS Admin. Expenses		984,000
Anticipated Adjustment		82,459
Total Commodity Entitlement	288,763,045	\$162,328,990
BONUS COMMODITIES		
SECTION 416-TYPE:		
BUTTER	61,783,380	\$57,386,803
CORNMEAL	48,967,250	5,938,043
Anticipated Adjustment	0	0
Total Section 416-Type	110,750,630	\$63,324,846
GRAND TOTAL (Entitlement & Bonus)	399,513,675	\$225,653,836

SOURCE: Preliminary food orders for fiscal year 1993.

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FOOD AND NUTRITION SERVICE

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

Food Program Administration:

For necessary administrative expenses of the domestic food programs funded under this Act, [~~\$107,767,000~~] \$106,983,000, of which \$5,000,000 shall be available only for simplifying procedures, reducing overhead costs, tightening regulations, improving food stamp coupon handling, and assistance in the prevention, identification, and prosecution of fraud and other violations of law: Provided, That this appropriation shall be available for employment pursuant to the second sentence of section 706(a) of the Organic Act of 1944 (7 U.S.C. 2225), and not to exceed \$150,000 shall be available for employment under 5 U.S.C. 3109.

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FOOD PROGRAM ADMINISTRATION

Appropriations Act	\$107,767,000
Budget Request, 1995	<u>106,983,000</u>
Decrease in Appropriation	<u>-784,000</u>

SUMMARY OF INCREASES AND DECREASES

(On basis of appropriation)

Item of Change	1994	Pay Cost	Program	1995
	Estimated		Changes	Estimated
Salaries and Expenses..	<u>\$107,767,000</u>	<u>\$908,000</u>	<u>-\$1,692,000</u>	<u>\$106,983,000</u>

PROJECT STATEMENT

(On basis of appropriation)

Project	1993 Actual		1994 Estimated		Increase or Decrease	1995 Estimated	
	Amount	Staff: Years	Amount	Staff: Years		Amount	Staff: Years
1. Child Nutrition/..							
Special Milk.....	\$27,289,000:	470:	\$28,516,000:	470:	-\$213,000:	\$28,303,000:	468
2. Supplemental							
Feeding.....	11,117,000:	195:	11,875,000:	195:	-86,000:	11,789,000:	194
3. Food Stamp.....	57,987,000:	989:	60,319,000:	989:	-430,000:	59,889,000:	988
4. Food Donations....	6,634,000:	115:	7,057,000:	115:	-55,000:	7,002,000:	115
Unobligated							
balance lapsing..	508,000:						
Total available or ..							
estimated.....	103,535,000:	1,769:	107,767,000:	1,769:	-784,000:	106,983,000:	1,762

EXPLANATION OF PROGRAM

The Food Program Administration (FPA) appropriation funds Federal salaries and expenses necessary for the Food and Nutrition Service (FNS) to administer the U.S. Department of Agriculture's (USDA) domestic food assistance programs.

Overview. FNS was established August 8, 1969 to administer the domestic food assistance programs. The programs' goals are to provide needy persons with access to a more nutritious diet, to improve the eating habits of the nation's children, and to help America's farmers by providing an outlet for the distribution of foods purchased under farmer assistance authorities.

USDA began food distribution programs more than fifty years ago and used a variant of the current Food Stamp Program in the 1930's. Over the years, the programs shown in the following table were established and are currently in operation. Most FNS programs are operated in a Federal/State partnership, with State and local agencies administering the program at the actual delivery level. The general complexity of the programs and the number of State entities that FNS must work with are key factors influencing FPA costs.

Year Begun	Program Name	Number and Types of Non-federal Partners
1946	National School Lunch Program (NSLP)	58 State Education Agencies 54 Food Distribution Agencies (Also, 20,000 School Food Authorities) (Essentially the same as NSLP)
1955	Special Milk Program	
1961	Food Stamp Program	53 State Agencies 208,000 Authorized Firms 10,000 Financial Institutions 37 Federal Reserve Banks
1965	Nutrition Program for the Elderly	57 State Agencies

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Year Begun	Program Name	Number and Types of Non-federal Partners	
1966	School Breakfast Program	(Essentially the same as NSLP)	
1968	Child and Adult Care Food Program	54 (Essentially the same as NSLP)	
1969	Summer Food Service Program	53 (Essentially the same as NSLP)	
1969	Commodity Supplemental Food Program	20	State Agencies
1972	Special Supplemental Food Program for Women, Infants, and Children (WIC)	84	State Agencies (Also, 45,500 Food Retailers)
1976	Food Distribution Program on Indian Reservations	6	State Agencies
		88	Indian Tribes
1981	The Emergency Food Assistance Program	55	State Agencies
1982	Nutrition Assistance Program for Puerto Rico	2	State Agency
1983	National Commodity Processing Program	11	Food Processors
1988	Soup Kitchen/Food Bank Program	55	State Agencies
1989	Farmers Market Nutrition Program	11	State Agencies

Responsibilities. FNS is responsible for paying the benefit costs and for paying a part of State administrative expenses for most food assistance programs. Depending upon how States have chosen to administer their part of the Federal/State partnership, FNS may work with the State department of human services, department of health, department of education, department on aging, department of agriculture, and/or State level commissions or other administrative units. When State law prohibits a State from disbursing program funds or where no State agency has assumed administrative responsibility, FNS assumes operation of the programs. In some programs, Indian tribal organizations function as State administering agencies.

FNS plans and coordinates the acquisition and distribution of purchased commodities to State agencies for use in domestic food assistance programs. FNS also distributes as bonus commodities surplus and price support commodities purchased for farm economic support purposes.

FNS implements program statutes through promulgation of regulations and instructions. FNS staff provide training and assistance to State Agencies, assure proper funds allocation and control, conduct program monitoring and evaluation, and develop program policy.

Streamlining the Agency.

Consistent with the President's directive dated September 11, 1993, recommendations of the Vice President's National Performance Review, and the Secretary's reorganization plan, the Food and Nutrition Service is developing plans to streamline its operations, increase efficiency, and minimize bureaucracy. Specifically,

- o The Office of the Consumer Advisor will be merged into the Food and Nutrition Service as a staff office (Office of Consumer Affairs) reporting to the Administrator, creating the Food and Consumer Service (FCS).
- o FNS will employ a "lead agency" concept, with FCS providing financial management and administrative management services to FCS and the Nutrition Research and Education Service (formerly HNIS). The Deputy Administrator for Management, FCS, and the Comptroller, FCS, will report to the FCS Administrator. All functions managed by the Assistant Secretary for Administration and the Chief Financial Officer at the Department level will be mirrored in the functional assignments to the Deputy Administrator for Management and the Comptroller at the Agency level.
- o Staffing levels at Headquarters will be reviewed, followed by reviews at field and regional offices. The Deputy Assistant Secretary has toured all Regional Offices and will be making specific recommendations with regards to field office changes in addition to 8 offices currently planned to be closed.

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- o Personnel requirements will be reduced through reorganization and improvements in efficiency. By the end of 1995, FCS will reduce its staffing level from 1,921 to 1,915 and thereafter to 1,910, 1,890, and 1,850 in 1996, 1997 and 1998 respectively.

Organization. Administrative functions of FNS are managed by an Administrator, two Associate Administrators and five Deputy Administrators. Each Deputy Administrator is responsible for management of program or administrative functions, as follows:

- Food Stamp Program - program planning, development and oversight related to the Food Stamp Program including monitoring retail store compliance and conducting investigations through field locations.
- Special Nutrition Programs - program planning, development and oversight for Child Nutrition, Supplemental Food Programs, Food Donations Programs, National-Commodity Processing and nutrition and technical services.
- Financial Management - accounting, budget, grants management, administrative review and program information functions for all FNS programs.
- Administrative Management - personnel, civil rights and equal employment opportunity, information resource management, management information, procurement, property and general administrative services.
- Office of Governmental Affairs and Public Information - liaison with Congress, media and the public and informational support of FNS programs; also, provides coordination of the FNS response to disasters.

Also at Headquarters is one staff office:

- Office of Analysis and Evaluation - conducts policy research and analysis; supports legislative analysis, budget planning and regulatory review across programs; and conducts special studies and evaluations.

Since this structure is substantially consistent with the Secretary's reorganization plan, only minor changes are currently contemplated.

Program operations are managed through seven regional offices, each directed by a regional administrator, incorporating 2 sub-regional offices, 64 field offices, and 18 additional satellite locations. These offices maintain direct contact with State agencies which administer the FNS programs and also conduct on-site management reviews of State operations and the 208,000 firms authorized to accept food stamps.

For Fiscal Year 1994, FNS will concentrate on improving program administration, streamlining and operations (within existing law). The agency believes that greater emphasis on all aspects of program integrity and efficiency will result in improved benefit delivery to recipients. Major areas of emphasis in the administration of FNS programs include:

Food Stamp Program

- Continue approving and monitoring State agencies' implementation of Electronic Benefit Transfer plans (EBT), and participating in interagency efforts to develop a multi-state EBT prototype.
- Continue implementation of the Mickey Leland Childhood Hunger Relief Act P.L. 103-66, which made many necessary improvements in the Food Stamp Program.
- Continue development of procedures to increase coordination of services among the Aid to Families with Dependent Children, Medicaid, Supplemental Security Income Programs, and the Food Stamp Program.
- Implementation of a long-term multi-pronged strategy to increase and enhance retailer integrity enforcement actions including the conclusion of the reauthorization of retailers project begun in Fiscal Year 1992, and to provide program modifications which will help deter food stamp trafficking.
- Continue efforts at the national and regional office level to assist State agencies in reducing errors in certification, benefit determination, and issuance.

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- Continue working on the five year plan for nutrition education for the Food Stamp Program. Encourage more States to include nutrition education components in their State plans and operations. Complete the development and print 5 million copies of a low-literacy nutrition education brochure and 10,000 posters introducing the Food Guide Pyramid to Food Stamp Program participants. A companion low literacy publication that addresses wise food shopping, basic food preparation tips and the new nutrition facts label is being developed. Monitor the Food Stamp Nutrition Education Demonstration Grants which are to be completed in Fiscal Year 1995.

Special Nutrition Programs

Child Nutrition Program

- Undertake major regulatory initiative to improve the quality of school meals consistent with the U.S. Dietary Guidelines.
- Implement Nutrient Standard Menu Planning (NSMP) demonstration project in 35 school food authorities; finalize workbooks and multi-media training materials and hold 4 workshops to train regional, State and local staffs.
- Continue development and testing of new school lunch recipes; contract for promotional package; and print and disseminate recipes.
- Continue to implement the Nutrition Education and Training (NET) Strategic Plan by developing a Needs Assessment Guide, conducting regional training workshops, developing Evaluation Guidelines, and pursuing partnership opportunities to achieve national strategic goals.
- Continued operation of the demonstration project to evaluate the participation of proprietary child care centers in the Child and Adult Care Food Program.
- Continued operation and expansion of the homeless demonstration project to evaluate the feasibility of providing Federal child nutrition funding for meals served to children in homeless shelters.
- Continued operation of the pilot programs designed to evaluate various alternatives to the meal counting and free and reduced price application requirements.
- Publish final regulations for direct certification of free meal eligibility in the National School Lunch Program.
- Continue technology transfer efforts in the National School Lunch Program and School Breakfast Program through Best Practice Awards.
- Provide staff support and technical assistance for the Nutrient Standard Menu Planning Demonstrations.

WIC Program

- Develop a revised Funds allocation formula to promote equitable distribution of appropriations among WIC State agencies.
- Continue coordination with the public health care community at large to prepare WIC for sustained rapid growth toward eventual full funding.
- Print and distribute the publication, entitled "Infant Nutrition and Feeding: A Reference Handbook for Nutrition and Health Counselors in the WIC and CSFP Programs." This handbook is designed to assist WIC and CSFP State and local agency staff in providing staff in-service nutrition education and individual and group nutrition education to WIC and CSFP participants on the subject of infant nutrition.
- Continue implementation of WIC vendor management improvement initiatives and proposed and final regulations to strengthen the integrity of vendor selection, training, monitoring and sanctioning.
- Develop a WIC model education program with supporting materials on breastfeeding promotion, immunization, tobacco counseling, and an exit counseling brochure for those recipients no longer eligible for the WIC Program.

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- Continued implementation of the Farmers' Market Nutrition Program, including grant awards, training and issuance of interim regulations.
- Continue implementation of Public Law 102-512, the WIC Infant Formula Procurement Act of 1992 through Federal solicitation of infant formula rebate bids and issuance of a report to Congress on the impact of this law on reduction in infant formula costs.

Commodity Programs

- Continued enhancement of the Processed Commodity Information Management System (PCIMS) which established one database for three USDA Agencies to use to manage the commodity programs and makes the programs more responsive to recipient agencies.
- Continue implementation of the Commodity Distribution Reform Act, P.L. 100-237, that mandated food distribution program enhancements which will make the system more responsive to recipient agencies.
- Continue in development of lower fat commodity products to assist schools and other outlets in achieving standards of the U.S. Dietary Guidelines.

Financial Management

- Improve the accounting and collection of debts, including the expansion of the Federal Tax Offset Program from 9 States in 1993 to 21 States in 1994. In 1995, the Agency anticipates another 12 to 15 States will be included.
- Implement a system for managing the processing of nonprocurement suspension and debarment actions to respond quickly and effectively to the need to protect Federal program resources.
- Continue development and implementation of the Agency Financial Management System: Correct current weaknesses in the system; implement the grants Management subsystem; and develop formal policy instructions and operating procedures.
- Develop a plan to centralize accounting station activities to save resources and maximize efficiency and consistency across all programs and regions.
- Implement procedures for inter-agency commodity reconciliation and accounting.
- Continue efforts to work with States on accounting for and collecting Food Stamp Program recipient claims. Develop accounting standards, instructions, and application software for recipient claims accounting.
- Establish and coordinate an Agency Performance Measures Working Group to support ongoing implementation of the requirements of the Chief Financial Officers Act of 1990 and the Government Performance and Results Act, P.L. 103-62.

Administrative Management

- Obtain Departmental approvals for EBT, Electronic Data Interchange and Business Process Re-engineering initiatives to further extend the FNS information structure.
- Develop National Integrated Quality Control System (NIQCS) contract for FNS, Administration on Children and Families (ACF) and Health Care Financing Administration (HCFA) including obtaining Delegated Procurement Authority/Technical Approval for hotline, hardware and software support.
- Coordinate with Department of Health and Human Services to implement the General Accounting Office recommendations relevant to improving the approval process for automation of State systems.
- Provide guidance and training on improved methods of using past performance information when assessing contractor proposals, as required by Office of Federal Procurement Policy (OFFPP) Policy Letter 92-5 and the Federal Acquisition Regulation.
- Develop additional EBT guidance for Regional Offices and State agencies in the form of Model EBT Request for Proposal (RFP) Guidelines and EBT chapter for FNS' Advance Planning Document (APD) Handbook.

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- Provide Information Resource Management (IRM) support to expand the Federal Tax Refund Offset Program from 9 to 21 States. Another 15 States are anticipated to join the Program in FY 1995.
- Improve technical evaluation criteria and methods for applying these criteria in evaluating a contractor's proposal.
- Improve guidance for research contract Statements of Work to increase the utilization of fixed-price contracts.
- Establish plan and monitor process implementing Executive Order 12861 to reduce civilian internal management regulations by 50 percent by September 11, 1996.
- Develop and offer Agencywide ethics training, as mandated by regulation.
- Continue enhancements to Store Tracking and Authorization Redemption System (STARS), and other Software Renewal Program maintenance activities.
- Implementation of Executive Order Number 12871 on Labor Management Partnerships.

JUSTIFICATION OF INCREASES AND DECREASES

- (1) A net decrease of \$784,000 for salaries and benefits and other expenses consisting of:

- (a) An increase of \$908,000 for the Fiscal Year 1995 pay raise.
- (b) A decrease of \$685,000 for a reduction in Federal employment.

Need for change. In support of the President's Executive Order mandating a reduction of 252,000 Federal positions by Fiscal Year 1998, FNS is eliminating three percent of its Fiscal Year 1993 personnel positions by the end of Fiscal Year 1995.

Nature of change. To achieve this reduction, FNS reduced its Fiscal Year 1994 staff year ceiling from 1,979 to 1,921. FNS will further reduce its staffing ceiling in Fiscal Year 1995 to 1,915.

<u>Activity</u>	<u>1993 Ceiling</u>	<u>1994 Revised Ceiling</u>	<u>1995</u>
			<u>Ceiling</u>
Food Program Administration	1,827	1,769	1,762
Child Nutrition Programs	127	127	118
Food Stamp Program	25	25	35
TOTAL FNS STAFF-YEARS	1,979	1,921	1,915

- (c) A decrease of \$1,007,000 for administrative efficiency.

Need for change. In support of the President's Executive Order to promote the efficient use of resources for administrative purposes, FNS is committed to reducing administrative costs.

Nature of change. Although some costs, such as utilities and equipment have increased, FNS will reduce total discretionary expenses by \$1,007,000 in Fiscal Year 1995 in areas such as travel and other services.

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FOOD PROGRAM ADMINISTRATION

STATUS OF PROGRAM

The Food Program Administration appropriation provides Federal operating expenses for administering the food assistance programs of the Food and Nutrition Service (FNS). Included under this account are the following programs: Food Stamp, Child Nutrition, Special Milk, Special Supplemental Food Program for Women, Infants, and Children (WIC), Commodity Supplemental Food, Food Donations Programs for Selected Groups, Nutrition Assistance for Puerto Rico, Surplus Commodity Donations activities, The Emergency Food Assistance Program, and National Commodity Processing. Major administrative activities of the FNS staff during Fiscal Year 1993 are as follows:

Food Stamp Program

The Food Stamp Program is in operation in all 50 States, the District of Columbia, the Virgin Islands and Guam. Its purpose is to give low income households access to a better diet by increasing their food purchasing power. The State agencies are responsible for certifying eligible households and issuing food stamps. The major activities performed by FNS include: developing policies and procedures for the administration of the program, providing technical assistance to State agencies, reviewing State agency quality control activities, determining the effectiveness and efficiency of State agency administration, reviewing and approving planning documents for computer system acquisitions and electronic benefit transfer issuance systems, and allocating employment and training funds to the State agencies. In addition, FNS directly authorizes the retail and wholesale firms which are approved to accept food stamps; controls the printing of food stamps and the distribution to State agencies; maintains fiscal accountability for food stamps issued to participants; and, in cooperation with the Federal Reserve System, establishes processes for the redemption and destruction of food stamps.

During Fiscal Year 1993, FNS performed the following principal Food Stamp Program administrative activities:

- Proposed major legislation to significantly increase food stamp benefits, simplify and improve program administration and help assure program integrity.
- Continued work on several demonstration projects directed toward program simplification, testing alternative systems for issuing food stamp benefits, demonstrating the effectiveness of conforming the food stamp Employment and Training Program to AFDC's Jobs Program, testing various welfare reform plans, and awarding outreach grants.
- Issued 2 proposed and 2 final regulations and 5 general notices.
- Acted upon 183 waiver requests, approving 154 and denying 29. Waivers of the regulations were requested in order to provide State agencies maximum flexibility to administer the program more effectively and efficiently.
- Continued support of State Agency efforts to implement Electronic Benefit Transfer Systems as alternative issuance methods.
- Coordinated the exchange of information on program management initiatives among State agencies by funding interstate exchange of expertise.
- Conducted regional error reduction conferences and awarded payment accuracy demonstration grants.
- Continued litigation and other action on quality control sanctions; continued litigation on other program issues.
- Approved 53 Employment and Training (E&T) Program State plans, allotted Federal funds for employment and training activities, and provided State agencies with guidance on E&T Program operations.
- Distributed reports on Compliance Branch investigations of retailers authorized to accept food stamps from recipients. The Compliance Branch sends these reports of its investigations of retail food stores to FNS regional offices, for appropriate administrative sanction actions, or to the Department's Office of Inspector General when it is determined that the potential for criminal prosecution exists.

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- Investigated 4,644 stores for violations. Of this number, 2,147 of the stores were found to be violating Food Stamp Program regulations (46 percent), and 1,387 (30 percent) of the investigations disclosed violations serious enough to warrant disqualification or other sanction action by FNS. The remaining 760 violating firms received official warning letters.

Nutrition Assistance for Puerto Rico

For Fiscal Year 1993, Puerto Rico spent: \$1,008.71 million in benefits to clients participating in its Nutrition Assistance Program; \$29.149 million (Federal funds) to administer the program; and \$10.825 million for the Commonwealth's Tick Eradication special project, for a total Federal expenditure of \$1.049 billion.

Child Nutrition and Special Milk Programs

The Child Nutrition Programs--the National School Lunch, School Breakfast, Summer Food Service and Child and Adult Care Food Programs--serve nutritious meals to needy and other children attending eligible schools, child care institutions, and summer recreational programs. FNS works primarily through State agencies, providing cash and commodities for use in preparing and serving meals. FNS furnishes administrative and program assistance to State agencies and participating schools and institutions. FNS also develops the policies, procedures and standards used in administering the programs and determining eligibility.

The FNS regional offices directly administer the National School Lunch and School Breakfast Programs for residential child care institutions and private schools where the State educational agency does not disburse funds. FNS regional offices also directly administer the Summer Food Service Program and the Child and Adult Care Food Program for nonresidential child care institutions where no State agency has assumed administrative responsibility. Because of the great number and small size of individual centers and sponsors of day care homes participating in States directly administered by FNS Regional Offices, adequate review of participating sponsors requires extensive FNS staff resources. The Summer Food Service Program also continues to place heavy demands on Federal personnel due to the short term of the program and because FNS must directly administer the program in six States.

In Fiscal Year 1993, FNS directly administered the National School Lunch and School Breakfast Programs for private schools in four States, private residential child care institutions in five States, and public residential child care institutions in two states. In addition, FNS operated the Child Care Food Program in Virginia and, until April, in New York and the Summer Food Service Program in six States (New York, Virginia, Georgia, Michigan, Missouri and California).

During Fiscal Year 1993, FNS performed the following principal activities in the Child Nutrition Programs:

- Conducted a pilot demonstration project to determine the best means of providing year round food assistance to homeless preschool children in shelters. The project was mandated by the Child Nutrition and WIC Reauthorization Act of 1989, P.L. 101-147; and in accordance with the reporting language, the project was initiated with the Archdiocese of Philadelphia, and has been expanded to include 64 organizations serving 93 homeless shelters nationwide. Public Law 102-342, enacted on August 14, 1992 authorized increased funding for the project and made public organizations eligible for it. One public entity is currently participating.
- Conducted two statewide demonstration projects to test eligibility changes in the Child and Adult Care Food Program. Under this project private for-profit centers may participate if they serve a minimum of 25 percent free or reduced price meals to children. The project is examining nutritional improvements, fees charged to low income children, numbers of additional low income children served, budgetary impact of the eligibility change, and effectiveness of State outreach methods. Pursuant to P.L. 101-147, Kentucky and Iowa were the States selected for these projects.
- Developed procedures and systems to evaluate and process cases subject to the Department's Nonprocurement Suspension and Debarment Authority. Liaison relationships have been established with the Department of Justice and Defense Logistics Agency and FNS has initiated additional training of State and local Program cooperators and increased monitoring activities by FNS. Due to an increase in nonprocurement suspension and debarment case-referrals in Fiscal Year 1993, FNS activity with respect to nonprocurement suspension and debarment actions has increased greatly. FNS has received information concerning criminal milk bid-rigging activity on approximately 50 cases of companies and individuals

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that may result in a suspension or debarment action. As of January 31, 1994, FNS has taken administrative action in 13 cases in accordance with its authority under the governmentwide Common Rule on Nonprocurement Debarment and Suspension. Two dairies were notified that debarment proceedings would not be initiated due to the protection to FNS programs granted under the Administrative Agreement the companies entered into with the Defense Logistics Agency. FNS intends to continue aggressive action on all cases involving firms or individuals found guilty of milk bid rigging.

- Initiated a major, multi-year effort to improve the nutritional quality of school meals. This effort which will include, among other things, conducting a series of public hearings, soliciting public comment, issuing information to State and local program cooperators, is directed towards bringing school lunches into conformance with the 1990 Dietary Guidelines for Americans.
- Continued ongoing demonstrations in nine school districts testing alternatives to current requirements governing determinations of eligibility for free and reduced price meals, and counting and claiming of those meals for reimbursement. This initiative was authorized under P.L. 101-147.
- Solicited proposals from States for grants to defray nonrecurring costs associated with starting up the School Breakfast Program. Awarded \$5 million to 27 States for the fourth year.
- Effective April 1, 1993, the New York State Department of Health assumed responsibility for administration of the Child & Adult Care Food Program in New York from FNS. FNS now directly administers the CACFP in one state -- Virginia.

The Special Milk Program provides cash to States to subsidize milk served to children in eligible nonprofit schools, child care centers, summer camps and similar institutions that do not participate in other Child Nutrition Programs and in certain schools with split session kindergartens. FNS directly administers the program for outlets in States which do not disburse funds to some participants, and for other outlets where no State agency has assumed administrative responsibility. During Fiscal Year 1993 FNS directly administered the Special Milk Program for private schools, summer camps and other institutions in six States.

Special Commodity Initiatives

FNS, in cooperation with the Agricultural Marketing Service and the Agricultural Stabilization and Conservation Service, initiated a long-term project called the Special Commodity Initiative to improve the distribution and quality of commodities in Child Nutrition Programs. FNS performed the following Special Commodity initiatives during Fiscal Year 1993:

- Implemented changes in operations and procurement cycles to improve inventory management and reduce storage costs.
- Continued the nutrition improvement efforts on the review of current specifications to obtain the lowest possible fat, salt and/or sugar levels while maintaining acceptability, functionality and consistency with dietary guidelines.
- Offered new commodities, such as ribbed-shaped patties, chicken patties, and salsa.
- Continued to improve shipment of commodities through increased use of unitization and better communications.
- Strengthened funds control through documenting and implementing commodity procurement reconciliation procedures within FNS and concluding reconciliation of all outstanding prior years among the three Agencies.

Special Supplemental Food Program for Women, Infants, and Children (WIC)

The WIC Program provides nutritious supplemental foods, nutrition education, and health care referrals through local health clinics to low income pregnant, postpartum, and breastfeeding women, and to infants and children up to five years of age who are found to be at "nutritional risk." FNS provides grant funds to State Departments of Health and others to permit the issuance of supplemental food instruments to eligible participants and pays for specified administrative costs including the cost of nutrition education. FNS also develops the policies, procedures, and standards used in administering the program and monitors State agency operations. In Fiscal Year 1993, the WIC Program was administered by 85 State agencies, including 50 States, 31 Indian agencies and the District of Columbia, Puerto Rico, Guam and the Virgin Islands.

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In Fiscal Year 1993, FNS performed the following principal activities:

- Conducted the annual meeting of the National Advisory Council on Maternal, Infant and Fetal Nutrition.
- Conducted a national training meeting on program requirements for the new WIC Farmers Market Nutrition Program.
- Conducted a nationwide technical assistance meeting for WIC State and local program operators on delivering quality nutrition services to a diverse WIC population.
- Issued two final regulations: 1) establishing an enhanced food package for breastfeeding women; 2) delineating WIC's role in screening participants and making referrals to drugs and other harmful substance abuse counseling, treatment and education programs.
- Issued an interim final regulation for USDA solicitation of bids for infant formula rebates.
- Cooperated with DHHS on a number of maternal and child health promotions.
- Conducted a nationwide meeting of WIC Immunization Program Managers along with the Centers for Disease Control and Prevention to promote immunizations among the WIC population.
- Conducted two meetings of the Breastfeeding Consortium, a USDA-established collaborative effort which brings together almost 30 professional health organizations and government agencies on a regular basis to discuss breastfeeding promotion strategies.

Commodity Supplemental Food Program (CSFP)

The Commodity Supplemental Food Program provides supplemental food to low income pregnant, postpartum and breastfeeding women, infants, children up to age six and the elderly. The foods are purchased directly by the Department of Agriculture and are distributed through State and local agencies. Major activities during Fiscal Year 1993 included: Planned and conducted a nationwide technical assistance meeting on current issues and future opportunities in recognition of the silver anniversary of the program; determined of the quantity of food required and the allocation of commodities to meet the requirements; coordinated interagency commodity purchases; conducted program monitoring and review; and assured the allocation of funds to States for administrative costs. During Fiscal Year 1993, the Commodity Supplemental Food Program was operated through 20 State agencies.

Food Donations Programs for Selected Groups

Commodity programs which provide direct assistance to persons in need include: the Food Distribution Program on Indian Reservations, the Nutrition Program for the Elderly, and Soup Kitchen/Food Banks assistance.

- Food Distribution Program on Indian Reservations (FDPIR)

FNS acquires and distributes agricultural commodities to needy persons and families on Indian reservations through FDPIR provided they do not receive food stamps. Cash assistance is also provided to help finance the administrative cost of operating the program.

The Food Stamp Act of 1977, which requires that a food distribution program be operated on Indian reservations that request it, also allows the Indian reservations to run FDPIR provided they meet specified administrative criteria. FNS provides the training and other assistance as needed.

Training and other assistance provided to new reservations are primarily directed toward basic program operations, while the assistance given to more experienced reservations concentrates on the enhancement of program management.

- Nutrition Program for the Elderly

The Nutrition Program for the Elderly provides commodities and cash-in-lieu of commodities for meals served in senior citizen centers and similar settings where participants can also receive social and rehabilitative services. The management and operation of this program is in the Administration on Aging (AOA) of the Department of Health and Human Services (DHHS). The meals served are the focal

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point for the nutrition projects which have the dual objectives of promoting better health and reducing the isolation that may occur in old age. The activities performed by FNS are receiving and processing States' orders for commodities and providing the commodities and cash-in-lieu of commodities.

- Soup Kitchen/Food Banks

Pursuant to the Hunger Prevention Act of 1988, Public Law 100-435, \$32 million was appropriated for Fiscal Year 1993 to purchase, process, and distribute commodities to soup kitchens and food banks. In Fiscal Year 1993, approximately 51.7 million pounds of commodities valued at \$32 million were purchased and made available to States for distribution to soup kitchens and food banks.

Surplus Commodity Donations to Charitable Institutions and Summer Camps

The Surplus Commodity Donations Program provides commodities to nonprofit charitable institutions serving needy persons and to summer camps for children. These commodities are provided under section 416 Commodity Credit Corporation price support operations and section 32 surplus removal activities. Among the charitable institutions receiving donated commodities are homes for the elderly, hospitals, soup kitchens, meals-on-wheels programs, and orphanages that do not participate in one of the Child Nutrition Programs. FNS works through State agencies to provide these commodities. FNS furnishes administrative and program assistance to the cooperating State agencies and also develops the policies, procedures and standards used in administering the programs and determining eligibility.

The Emergency Food Assistance Program

FNS allocates administrative funds and commodities to States based on the number of unemployed persons and the number of persons with incomes below the poverty level within each State. During Fiscal Year 1993, FNS distributed \$45 million for administration and \$161.3 million worth of commodities were purchased and donated including \$42.3 million of one-time assistance for the purchase of commodities under P.L. 102-552. In addition, \$63.3 million worth of surplus commodities from the Commodity Credit Corporation were donated.

Nutrition and Technical Services Support of Program Operations

The Nutrition and Technical Services staff provides technical support to FNS programs in the areas of nutrition science, nutrition education, food service management, and food/science technology. Nutritionists and food technologists at the Agency headquarters provide assistance and information to State and local agencies administering FNS programs.

During Fiscal Year 1993, the following activities were accomplished:

- Revised publication, Nutrition Guidelines for the Child Nutrition Programs, continues to be requested. The publication has been translated into Spanish and will soon be available to States and local schools.
- Continued to provide oversight and direct assistance services to the National Food Service Management Institute including participating in Board meetings and providing technical assistance to the Institute.
- Reviewed over 5,800 Child Nutrition (CN) labels. Continued conversion of CN labeling program to new software.
- Prepared final rule to approve the use of the Protein Digestibility corrected Amino Acid Score method to determine protein quality of enriched macaroni products with fortified protein used in the Child Nutrition Programs.
- Provided on-going technical assistance to the Food Distribution Division reviewing commodity specifications and State Operation Commodity contracts. Participated in a Task Force consisting of members from FNS, Agricultural Marketing Service and industry on future buys.
- Prepared final rule for competitive foods, replacing USDA's with RDI's.
- Published a public notice in the Federal Register of Nutrient Standard Menu Planning demonstration project. Received 126 applications from volunteer school districts to participate. Signed a cooperative agreement with HNIS to develop a National Nutrient Database for Child Nutrition Programs. Continued to work with California State Agency on development of training materials for the demonstration. Implementation is scheduled for September 1994.

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- Signed a Cooperative Agreement with Penn State University for the development and standardization of more than 50 new recipes for the National School Lunch and National Breakfast Programs. The project is to be completed in June 1994.
- Completed the development of the Infant Nutrition and Feeding Reference Handbook for Nutritionists and Health Counselors in the WIC and CSF Programs.
- Coordinated efforts to explore recruitment and retention strategies for nutritionists in Federal Child Nutrition Programs. Co-sponsored, along with several national organizations, the first of two workshops to discuss current difficulties and develop recruitment/retention strategies. A second workshop is planned for January 1994.
- Developed poster, pamphlet and fact sheets for use in promoting breastfeeding for children participating in the Child and Adult Care Food Program.
- Assisted with the planning, organizing and implementing of the 1993 National WIC Nutrition Services Conference.
- Planned and conducted the Annual Regional WIC Nutritionists Meeting in conjunction with the National WIC Nutrition Services Conference.
- Planned and conducted a National Nutrition Education and Training (NET) Conference which introduced the NET Strategic Plan for Nutrition Education.
- Awarded a contract for developing State NET Needs Assessment Guidelines. Guidelines should be available in January 1994.
- Signed a Memorandum of Understanding with the Food Stamp Program (FSP), assuming responsibility for developing a nutrition education plan for the FSP over the next three years.
- Tested household-size commodity recipes to be part of a "recipe file" used in conjunction with printed materials distributed in the commodity programs.
- Served on the Advisory Committee for the Padres Hispanic En Accion Head Start Project. Video and printed materials have been developed. Implementation through the NET Program is scheduled for 1994.

Regional Operations

Along with its headquarters in Alexandria, Virginia, FNS maintains seven regional offices, 80 field locations (field and satellite) and 3 ROAP offices (2 seasonal). In addition, there are six Food Stamp Compliance offices, four outstationed Administrative Review Offices and one computer support center in Minneapolis which report directly to headquarters.

The regional offices supervise the 80 field locations whose mission is to ensure compliance in the Food Stamp Program and provide various review and support services for the other food assistance programs. Each regional office provides leadership and direction in implementing FNS program policy, develops operational planning and strategy, maintains cooperative working relationships with State agencies, and executes State corrective actions when necessary. A regional office or field office may also directly administer programs for schools and residential child care institutions where State educational agencies do not administer the program, as well as programs in child care institutions and summer program sites where no State agency has assumed administrative responsibility. Because of its location, the Caribbean Area office (a field office in Puerto Rico) performs many Regional office functions including all the on-site review work for Puerto Rico and the Virgin Islands. Similarly the Hawaii field office does the same for the Pacific Islands.

The regional office sites and the States currently in each region are as follows:

Northeast Region

Boston, Massachusetts
Connecticut New York
Maine Rhode Island
Massachusetts Vermont
New Hampshire

Southwest Region

Dallas, Texas
Arkansas Oklahoma
Louisiana Texas
New Mexico

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Mid Atlantic Region

Robbinsville, New Jersey	
Delaware	Puerto Rico
District of Columbia	Virginia
Maryland	Virgin Islands
New Jersey	West Virginia
Pennsylvania	

Southeast Region

Atlanta, Georgia	
Alabama	Mississippi
Florida	North Carolina
Georgia	South Carolina
Kentucky	Tennessee

Midwest Region

Chicago, Illinois	
Illinois	Minnesota
Indiana	Ohio
Michigan	Wisconsin

Financial Management Initiatives

During Fiscal Year 1993, FNS executed the following financial management initiatives:

- Increased its oversight of the expansion of Electronic Benefit Transfer (EBT) projects. Training programs were completed for FNS Regional Office staff and an important evaluation of the New Mexico and Ramsey County EBT systems was published. State activity increased dramatically to approximately 35 States having some level of EBT activity--from early planning to actual operations.
- Continued to increase collections of delinquent food stamp recipient claims by expanding the Federal Income Tax Refund Offset Program. Seven states were added to the two which began the program. Through the end of Fiscal Year 1993, collections for the nine participating States totaled more than \$8 million.
- Continued to emphasize error reduction as a high priority issue. Activities in this regard have included: (1) letters from Secretary Espy to the 15 highest error rate States urging a stronger commitment to payment accuracy; (2) technical support through the Regional Offices and with the help of State Exchange funds to implement successful error reduction strategies; and (3) the awarding of demonstration grants to test the effectiveness of specific payment accuracy initiatives in high issuance areas.
- Continued to stress the importance of complying with the provisions of the Prompt Payment Act. During Fiscal Year 1993, the Agency processed 2,228 vouchers valued at \$10,127,293. Only \$588 in interest penalties were assessed.
- Continued the objective to install the Agency Financial Management System (AFMS) which replaces the Agency's accounts receivable, accounts payable, and Grants Management subsystems. After receiving the partial funding in Fiscal Years 1991 and 1992 the AFMS core accounting systems was implemented on schedule (October 1992) within Budget Division. This made FNS one of the first agencies to have implemented a new core accounting system that meets the Joint Financial Management Improvement Project (JFHIP) standards and requirements. Plans are to complete the development and implementation of AFMS subsystems (Grants Management, budget formulation, administrative funds, and performance measurement), and to provide on-going maintenance and support of the core system. No additional funding was specifically earmarked for AFMS development in the FY 1993 budget, although further work was necessary. AFMS maintenance and enhancements were required, as well as continued development of the grants management module.

Mountain Plains Region

Denver, Colorado	
Colorado	Nebraska
Iowa	North Dakota
Kansas	South Dakota
Missouri	Utah
Montana	Wyoming

Western Region

San Francisco, California	
Alaska	Nevada
American Samoa	Northern Marianas
Arizona	Oregon
California	Freely Associated States
Guam	Washington
Hawaii	
Idaho	

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Debt Management

Debts owed to FNS arise from several sources, such as:

- Audits, investigations and management evaluations of State and local agencies and nonprofit institutions which receive funding from FNS.
- Investigations of retailers and wholesalers participating in the Food Stamp Program, including assessment of civil penalties for program abuse and recoveries for improper redemption of food stamps.
- Losses of commodities which were transferred to commercial food processors prior to being shipped to States and losses of commodities distributed to States.
- Food Stamp coupons lost from State and local inventories, and losses resulting from State coupon issuances by mail.
- Claims against Food Stamp recipients for improper benefits.
- Claims against State agencies for erroneous issuances of food stamp coupons, and for error rates in State food stamp coupon issuance.
- Claims against school food authorities for meals charged inappropriately.

Highlights of Debt Management
Fiscal year 1992 - Fiscal Year 1993
(\$ Millions)

Debt Management (Excluding Food Stamp Recipient Claims):

	1992	1993
Accounts receivable, ending balance	47.9	61.1
Collections	33.4	44.8
Litigation	21.1	38.6
Past Due	2.8	14.0

Food Stamp Recipient Claims:

Accounts receivable, ending balance	722.4	819.6
Collections	106.1	100.0

Debt collection accomplishments include:

- Increased collection agency referrals by 75 percent from the previous year to \$3.5 million.
- Increased receivables billed to \$96.1 million; almost 62 percent greater than Fiscal Year 1992.
- Increased collections received by 34 percent from the previous year due in part to a \$9.4 million payment from New York for Food Stamp administrative costs.
- Increased accounts on installment payment schedules by 85 percent from Fiscal Year 1992 to \$14.4 million.

Administrative Management Initiatives:Information Resources Management

During Fiscal Year 1993 FNS continued to update its technologies and systems in support of Agency goals. Major activities included:

- Nearly all of the software systems identified in the FNS Software Renewal Program have been newly redesigned and are either on-line or nearing completion. The aggressive redesign of the 66 major software systems supporting financial areas, Special Nutrition Programs, and the Food Stamp Program has proceeded on schedule. The redesign was done so they could proceed relatively independently in order to minimize the risks of such extensive software development efforts.

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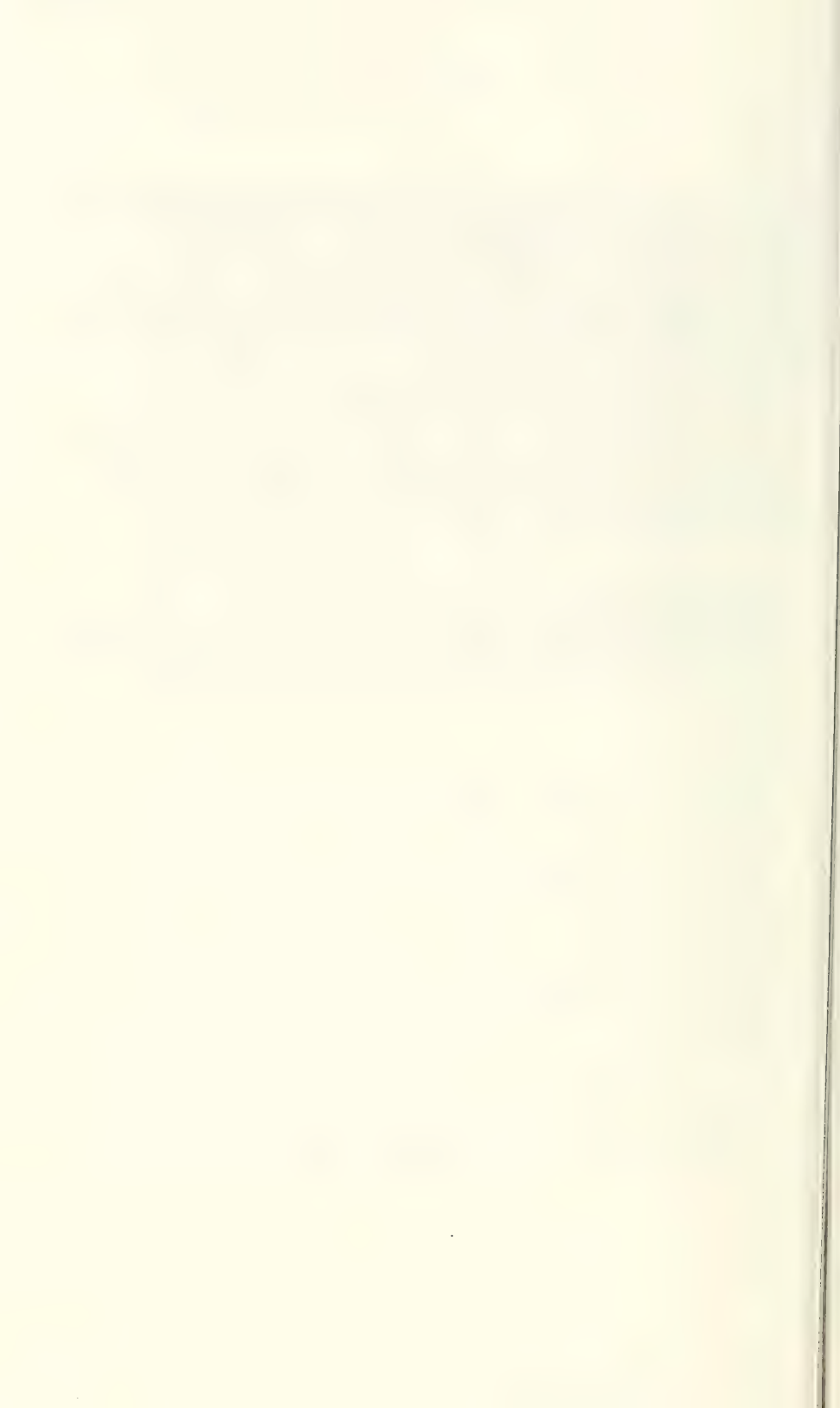
- FNS has completed Stages 1 and 2 of the Food Stamp Program Integrated Information System (FSPIIS), implementing all of the Food Stamp forms received from grantees and project areas. This implementation also included the Coupon Requisition and Inventory Management Subsystem (CRIMS). The Store Tracking and Redemption Subsystem (STARS) became operational in October 1993. STARS is an extension of the earlier Redemption Accountability Program (RAP) project which greatly improved the accountability of food coupons within the banking system. RAP and STARS are intended to provide vastly improved accountability support for the Agency's immense Redemption Account. Design, development, and implementation of a number of functional enhancements to STARS are planned during Fiscal Year 1994. The Special Nutrition forms received from State agencies, distributing agencies, and local agencies have also been implemented in the Special Nutrition Program Integrated Information System (SNPIIS) using a stages implementation strategy.
- The Agency proceeded with the development and implementation of State Connectivity (SCDEX) capability for Food Stamp and Child Nutrition Program reports. This initiative permits the electronic exchange of management information.
- Other software activities include the design and development of the Disqualified Recipient Subsystem (DRS). This subsystem provides a data base and software needed to support the collection and management of data on disqualified recipients throughout the United States. FNS has entered into an agreement with the Social Security Administration to use its File Transfer Management System as the network to transport DRS data. It will also support State queries into the data base via voice response units. State agencies are being phased into DRS during Fiscal Year 1993 and 1994.
- Under the current design of the Processed Commodities Inventory Management System (PCIMS), States mail orders to FNS regional offices where they are keyed into the system. States call FNS for information on the status of their orders and on the amount of benefits available. FNS plans to modify the system to allow states to input their portion of the order and to check on status information electronically. In addition, the system is being extensively modified to improve funds control and tri-agency accounting (Agricultural Stabilization and Conservation Service, Agricultural Marketing Service, and FNS).
- Purchased additional microcomputers for FNS headquarters, regional and field office staff.
- Installed fourteen 486 file servers throughout Park Center and installed one 486 file server in each regional office.
- Reviewed and concurred with approval for \$67.3 million from 19 Advanced Planning Documents (APD) for State systems development, implementation, and operations. Participated in the review of planning documents for EBT projects for 25 states.
- Processed 220 administrative printing requisitions. Reviewed and processed 35 information collection packages for OMB review and approval.
- Conducted FNS-wide Forms Reduction Campaign, eliminating 29 FNS forms. Created 8 new forms and revised 16 FNS forms on automated workstations. Automated 64 FNS, USDA, and Standard Forms.
- Conducted active records reduction program for the Agency. Issued FNS Notice Records Reduction Campaign-Operation Clean Sweep on June 23, 1993, resulting in 450 cubic feet of records removed.
- Conducted an annual review of FNS directives to cancel obsolete directives and revise outdated directives, resulting in 11 cancellations, 7 revisions, and over 100 slated for cancellation/updating during Fiscal Year 1994.
- Processed approximately 500 Freedom of Information Act requests and actions. Processed approximately 100 Privacy Act actions.
- Reviewed and processed 318 directives amounting to 2,814 pages.
- Reviewed and processed for publication in the Federal Register 103 regulations.

Personnel/Work Force Diversity

During Fiscal Year 1993, a number of programs and initiatives occurred throughout the Agency to create a more diversified work force as follows:

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- Funded three minority students under the Federal Junior Fellowship Program in the Washington, D.C. area and 13 minority students out of 20 students funded under the Cooperative Education Program.
- Employed three minority students under the Summer Intern Program.
- Employed 66 Stay-In-School students that were minorities out of a total of 79 students employed.
- Established service agreements with the Office of Worker's Compensation Program (OWCP) and OWCP recipients and provided on-the-job training to two OWCP recipients.
- Sponsored a student under the 1890/National Scholars Program.
- Fully implemented the Mentor/Protege Program.
- Provided \$30,000 start-up money to the World Food Distribution Training Center of Excellence of Prairie View University. The Center selected one of the Agency's senior managers to serve on its Board of Directors.
- Awarded five capacity-building grants to 1890 Land Grant Universities. Participated in the D.C. Summer Youth Program and hired 12 minority students.
- Provided mentors to the Department's adopted school in Washington, D.C., Van Ness Elementary School.
- Participated in regional summer youth programs and served as mentors in local schools.
- Developed an Agency orientation program for new employees.
- Converted all Food Program Specialist, GS-120 positions to the Program Specialist, GS-301, and Program Analyst, GS-343 series to broaden recruitment sources and advancement opportunities for present employees.
- Provided Sexual Harassment Training to over 800 employees in FNS and HNIS.



WEDNESDAY, APRIL 13, 1994.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

WITNESSES

PATRICIA JENSEN, ACTING ASSISTANT SECRETARY FOR MARKETING AND INSPECTION SERVICES

LONNIE J. KING, ACTING ADMINISTRATOR, ANIMAL AND PLANT HEALTH INSPECTION SERVICE

BOBBY R. ACORD, DEPUTY ADMINISTRATOR, ANIMAL DAMAGE CONTROL

DALE F. SCHWINDAMAN, DEPUTY ADMINISTRATOR, REGULATORY ENFORCEMENT AND ANIMAL CARE

CHARLES SCHWALBE, ACTING DEPUTY ADMINISTRATOR, PLANT PROTECTION AND QUARANTINE

MARSHALL KIRBY, ASSOCIATE DEPUTY ADMINISTRATOR, INTERNATIONAL SERVICES

GEORGE O. WINEGAR, ASSISTANT DEPUTY ADMINISTRATOR, VETERINARY SERVICES

JOHN H. PAYNE, ACTING DIRECTOR, BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

KEVIN SHEA, DIRECTOR, BUDGET AND ACCOUNTING DIVISION

STEPHEN B. DEWHURST, BUDGET OFFICER, DEPARTMENT OF AGRICULTURE

OPENING REMARKS

Mr. DURBIN. Good morning and welcome to the Subcommittee hearing for the Animal and Plant Health Inspection Service with Patricia Jensen returning for a reprise.

Mr. SKEEN. For a return engagement.

Mr. DURBIN. She is the Acting Assistant Secretary. And Lonnie King, Acting Administrator. There is a lot of acting going on down at USDA. And we want to get some straight answers from the real script. So we appreciate you joining us. And please when appropriate introduce your colleagues who are with us today as well.

Ms. JENSEN. Thank you, Mr. Chairman. It is a pleasure to return here again today.

Mr. Chairman, and Members of the Committee, I am here before you today to discuss the fiscal year 1995 budget proposals for the Animal and Plant Health Inspection Service APHIS.

APHIS protects American agriculture by preventing the introduction of destructive foreign plant and animal pests and diseases; by monitoring plant and animal health; by conducting programs to prevent, to detect, and eradicate harmful pests and diseases; and by developing methods to control animals and pests which threaten agriculture or constitute a public health or safety hazard.

It also administers the Animal Welfare Act to ensure that warm blooded animals used for research, exhibition, or sold wholesale as pets receive humane care and treatment.

With me today is the Acting Administrator of APHIS, Dr. Lonnie King. He has a prepared statement for the record, and will answer questions regarding our budget proposals, and will introduce the others at the table.

ACTING ADMINISTRATOR'S REMARKS

Dr. KING. Mr. Chairman, and Members of the Committee, I appreciate the opportunity to report on our continuing efforts to protect American agriculture, and its ability to affordably and safely feed Americans and others, and its contribution as part of the largest industry in our economy. I would like to report briefly on our agency's mission, organization, current activities, and the issues that we face.

First let me introduce some members of our management team with me today. They are Deputy Administrators Bobby Acord for Animal Damage Control, and Dale Schwindaman for Regulatory Enforcement, Animal Care; Mr. Marshall Kirby, Associate Deputy Administrator for International Services; Dr. Charles Schwalbe, Acting Deputy Administrator for Plant Protection and Quarantine; Dr. John Payne, Acting Director of Biotechnology, Biologics, and Environmental Protection; Dr. George Winegar, Assistant Deputy Administrator for Veterinary Services; and Mr. Kevin Shea, Director of the Budget and Accounting Division.

The mission of the Animal and Plant Health Inspection Service is to protect American agriculture by providing leadership in ensuring the health and care of animals and plants, and thus improving agricultural productivity and competitiveness. This primary objective helps to keep food safe, plentiful, and inexpensive. Our programs help keep our agricultural industry efficient, economically sound and successful, thereby contributing to our national economy and the public's health.

To achieve our mission, we must be sensitive and responsive to customers in the very broadest sense. Not just traditional agricultural commodity groups, but others who are directly or indirectly affected by our services.

Because of the general public's concern about food safety, we propose a pre-harvest pathogen reduction program. The goal of this program is to provide the consumer with safe, reliable, and affordable animal food products by reducing biological and chemical pathogens at the farm level. This proactive approach to increase the overall awareness of food safety from farm to table will lead to increased consumer confidence in the safety of this country's food supply.

International travelers are our customers as well. In fiscal year 1993, 47 million passengers arrived at U.S. ports, an increase of almost 7 million over the previous year. Passenger arrivals are projected to increase steadily with new terminals in Atlanta and Denver opening in fiscal year 1995.

To respond to the projected increased demand for inspection services including aircraft, vessels, and rail cars, user fee generated funding needs to be available for increased staffing and equipment, such as x-ray machines. These activities help protect the multi-million dollar agricultural industry customers, and to provide the least burdensome service possible to the international traveling public.

Considering our customers in the broadest sense, we are aware of the public's deep concern with issues such as animal welfare and wildlife.

Under the Animal Welfare Act, APHIS carries out activities designed to ensure humane care in the handling of animals used in research, exhibition, or in the wholesale pet trade. We place primary emphasis on inspection of facilities, investigations of complaints, reinspection of problem facilities, and training of inspectors.

The program implemented a comprehensive computerized inspection tracking system known as the Licensing Application Registration Information System throughout the country. This system increases program efficiency by providing an on-line data base on licensing, on registrants, as well as the capability for establishing a risk-based inspection ranking system.

The Animal Damage Control Program protects animal agriculture from detrimental predators, and other animals causing losses to agriculture and risk to public health and safety through identification, demonstration, and application of the most appropriate methods of control. For example, APHIS continues to work with the Texas Department of Health to seek solutions to the problem of canine rabies, which has spread to several counties in South Texas. Research and development of control techniques and devices for operational program and APHIS clientele are provided by the Denver Wildlife Research Center—DWRC. DWRC made progress in research to identify immunocontraceptives for use in deer and other mammals as a method to resolve site specific wildlife problems.

We continually anticipate and adjust for changes in the world that affect our ability to carry out the APHIS mission. A mission that has traditionally focused on preventing the entry of exotic pests and diseases must accommodate an increasing important role in facilitating U.S. agriculture exports.

APHIS maintains a presence in countries that are significant agricultural trading partners and these may be potential sources of economically dangerous agricultural pests and diseases. APHIS conducted pre-clearance inspection of fruit and vegetables in twenty-one countries worldwide. APHIS personnel at overseas locations provided an effective first line defense against the entry of foreign plant and animal diseases and pests into our country.

Domestically, in the animal health monitoring and surveillance program, APHIS works cooperatively with other entities to maintain the capability for consistent disease surveillance, detection, emergency disease preparedness and response, animal health monitoring, and epidemiologic delivery. Combining new technologies with enhanced cooperative involvement leads to program success. For example, we have used a computerized geographic information system to make great strides in the boll weevil eradication program. This program continues its steady progress with growers paying 70 percent of the cost.

The biotechnology program regulates the field release and interstate movement and importation of genetically modified organisms. The intent is to certify and ensure that the introduction and field testing of new products do not present potential risks to America's

plant and animal resources, its industries, the general public, or the environment.

Since 1987, the number of release permits for field tests of trans-genetic plants have increased from 5 to 141 in fiscal year 1993.

Making the most of limited resources is a challenge that we all face and requires innovation and just some old fashioned belt tightening. We must pursue better integration of functions and greater resource sharing; more facilitation and less controlling and promulgation of rules and regulations; and designing of innovative processes and programs that provide flexibility. As part of this effort, APHIS proposes to adjust its budget to reflect plant health functions performed. Currently, programs represent a specific plant pest, a pest prevention or control program, or technical support. The functional budget approach would provide for consistent pest exclusion, survey and monitoring, and scientific and technical services without direct ties to traditional plant and pest control programs. The structure would allow for continued survey and monitoring after pest eradication activities are completed. This budget adjustment is similar to the restructure of animal health activities that became effective in fiscal year 1994.

The request proposes \$436.4 million for salaries and expenses, a decrease of \$3.2 million from the fiscal year 1994 current estimate of \$439.6 million. Of the proposed amount, \$101.9 million would be derived from AQI user fees, an increase of \$10.4 million over the fiscal year 1994 level because of increased international traffic. APHIS proposes that fees collected in the AQI user fee account remain available without appropriation action to better provide services that are driven by demand. The budget requests \$7 million for buildings and facilities to fund repairs, alterations, and renovations at existing facilities and structures, the same as 1994 current estimate.

Since its inception, APHIS has played a crucial role in protecting American agriculture. In this role, we will continue to face many challenges relating to animal and plant pest and disease conditions, increases in agricultural production and trade, rising public concerns about food safety, environmental quality, and the humane treatment of animals. Because of changes in production, marketing, and public expectations, changes are needed in prevention, control, and eradication strategies. There is a shifting emphasis from animal and plant pest and disease control to one of animal and plant health, and a corresponding new emphasis on monitoring and surveillance to ensure the health and safety of agricultural products. We appreciate the committee's strong support for our programs in the past. We look forward to meeting the challenge of protecting and strengthening American agriculture in the future. I would be happy to answer any questions. Thank you, Mr. Chairman.

[CLERK'S NOTE.—The Acting Administrator's statement appears on pages 847 through 867. Biographical sketches for Dr. Winegar and Mr. Kirby appear on pages 868 and 869. The Explanatory Notes appear on pages 870 through 987.]

FRUIT FLY ERADICATION

Mr. DURBIN. Thank you, Dr. King.

We hear a lot of comments from governors around the country about Federal mandates and expenses imposed on States by the Federal Government. And yet most of these governors do not give credit when the Federal Government steps in and spends massive amounts of money, for instance yesterday to open up a freeway in Southern California in record time.

And I think that in terms of your agency, of the expenditures that are often made to, in fact, bolster if not provide absolutely essential research for the local economy. When I think of the efforts being made by APHIS in fruit fly eradication to keep the fruit and vegetable industry alive in California.

Can you give us some kind of an idea of the amount of money we are spending as a Federal Government, so that this important part of the California economy and the national economy can continue to flourish?

Dr. KING. Over the last five years, approximately \$70 million have been spent.

Mr. DURBIN. And that is directed from the Federal Government exclusively for the citrus industry primarily for the West?

Dr. KING. The fruit fly eradication program in California.

PINK BOLLWORM

Mr. DURBIN. And that is only one effort of many. Pink bollworm is another example that has a particular application in California and some of the Western States.

The reason that I bring those up too is not only so that we can put in perspective some Federal investments that are being made to the benefit of many of these States and their economies, but also for our good and close friends in the pork busters coalition that like to sit back and giggle at the names of some of these efforts.

Can you tell us what the pink bollworm research means in terms of the economy, cotton growers, and reduction of chemicals that are being applied?

Dr. KING. Mr. Chairman, the pink bollworm program has undergone a change in that a new sterile moth rearing facility has opened up in Phoenix, Arizona. We have spent appropriate funds on new equipment in the replacement facility to raise sterile moth as part of the bio-control aspect of this program.

We conduct detection surveys and carry out regulatory functions to control movements so the pink bollworm will not spread. And there is some indication that this is not just a California problem, but would be a problem in uninfested Southeastern cotton States. Although we are asking for a funding reduction from last year because the equipment for the replacement facility has been purchased we still have a major role to play in this cooperative program.

SCREWORM

Mr. DURBIN. Some private sources has estimated that we have reduced the application of chemicals in the San Joaquin Valley, because of pink bollworm research. The sources report reductions of one hundred million pounds of pesticides over twenty-five years of the program.

I do not think that story gets out. I think that a lot of people like our pork busters are not known for high IQs, but do get a lot of attention by the media. I would really like to focus in on the names of these projects without looking at the ultimate impact of what is involved.

Another one that they just think is hilarious is screwworm research. Tell us a little bit about that. I mean they really think that is a good line for David Letterman. They cannot understand why we would spend a penny on it.

Would you like to explain why we do?

Dr. KING. Yes. First of all, I saw the same article. The APHIS focus is not screwworm research. Our funding goes into the operations of the eradication effort. The Agriculture Research Service provides some basic research to facilitate the efficacy of the program and APHIS' role is to follow through on our commitment to move this ruinous threat as far from the U.S. Cattle Industry as possible. There are many who may not have been around or remembered what screwworm infestations were like when it ravaged the industry in the southern part of the United States. One picture would serve as a graphic representation of the condition.

It is a devastating problem. Essentially what occurs is the adult screwworm fly lays four to five-hundred eggs in an open wound or exposed umbilical cord, in the case of newborn calves, which soon hatch and become voracious live-flesh-eating maggots. To see the suffering of an adult animal or calf with that condition would make believers out of anyone.

We have eradicated the screwworm from the Southern United States, and we have cooperatively eradicated the screwworm from Mexico. The immensely successful biocontrol component of the program continues as we march against this pest down through Central America. All cooperating Central American countries, including Nicaragua where we are now releasing sterile flies, have successfully committed personnel, equipment, and limited funding to this effort.

Our goal is to establish and maintain a permanent barrier at the isthmus of Panama and to build a new sterile fly production facility there, so that screwworms do not migrate north from South America.

People do not realize that there is a significant human health problem involving screwworms. I have seen pictures of adults and children that contracted severe infestations of screwworms in hospitals where there are no screens. It is not a very pleasant sight. Also, I would like to provide some additional information for the record on a study that was done related to costs if the screwworm was reintroduced in the United States.

[The information follows:]

A 1973 study by Davis and Prater, estimated livestock mortality losses at \$121.7 million on an annual basis. In the same study, the reduction in "red meat" supply as a result of screwworm damage, would have cost the consuming public \$146.4 million. In translating these estimates into 1994 values, the annual producer loss would be approximately \$239.2 million annually, and the meat supply loss would be \$287.7 million. Direct costs would therefore total \$526.9 million annually. If forward and backward linkages in the economy due to secondary and tertiary sales of meat-related products are considered, the annual impact could be as high as \$1.8 billion. Also, screwworm is a human health danger, particularly to rural, low income residents.

The cost to eradicate the screwworm again from the United States would depend on the extent of the reintroduction and the time of year. A new outbreak similar to the last large outbreak of 1976, with up to 29,000 reported cases, would have the following impacts:

Control costs	\$35.0 million
Direct costs	263.2 million
Economic impact	921.2 million
Total impact	\$1.2 billion

USER FEES

Mr. DURBIN. Maybe we need to focus more on some of the cost benefits of this research so that the media, which blindly publishes all of these press releases from pork busters and taxpayer watch dogs, would at least pause for a moment and ask a question as to whether or not this research is valuable.

And I think that a lot of us, perhaps not Members of this Subcommittee but others in public life, have been a little too calm in our response to this. We cannot let this group of thick skulled individuals who call themselves public servants really dictate the debate.

Can I ask you about user fees for a moment here. We usually get requests for new user fees. And your agency as much as any seems to be moving toward utilizing more user fees.

Can you tell me currently what kinds of user fees are being applied, and what you anticipate in the next budget?

Dr. KING. The bulk of the user fees are in the agricultural quarantine and inspection program. We are also asking that fees collected in the AQI user fee account remain available without appropriation action. We also have user fees for diagnostic services in our laboratory in Ames, Iowa, and user fee collections for import/export work, as well as for importation of animal products.

The only section or activity that we have not come out with user fees yet is exportation of animal products. And those are being analyzed in preparation for being established. So it is becoming almost 25 percent of our budget.

Mr. DURBIN. Do you anticipate more user fees?

Dr. KING. In the agricultural quarantine and inspection program, we anticipate an increase in user fee financed services. This is because of the locality pay increase and the trends for increasing foreign travelers and cargo. No additional user fees are proposed in the budget request.

MIAMI AQI

Mr. DURBIN. You get a lot of complaints about the Miami Airport situation. You probably heard about them.

Can you tell us a little bit about this situation?

Dr. KING. The Miami port is probably the busiest that we have. And when we talk about the Miami port, we really talk about three different facilities. We talk about airport inspection, which has a lot of passenger traffic, many from South and Central America. Also, it is a maritime port, which has to inspect vessels, which is increasing at a rate of about 15 percent per year. And a plant inspection station that inspects all regulated live plants coming into the United States. About 85 percent of all of the live plants coming into the United States comes through that port.

Mr. DURBIN. Help me here. I visited a city, and I think it was Orlando, that has a brand new APHIS facility.

Is that correct, is my memory correct?

Dr. KING. It is a new part of that airport, and it also includes a new PPQ facility.

Mr. DURBIN. And it is virtually empty?

Dr. KING. Yes, relatively low cargo inspections.

Mr. DURBIN. Well, it turns out, they said, that when it was built that there was a lot of business and traffic into that airport. And it is beautiful and brand new. And now it sits empty, because everyone wants to fly into Miami. And the people in Miami are complaining about all of the delays. I am missing something here.

If I wanted to export products to the United States through Florida and did not want the delay in Miami, it seems like there is another airport available; am I correct?

Dr. KING. It also shows our difficulties to predict which of these airports and which of these facilities are going to be used. Miami is convenient, and we have experts in Miami that are able to facilitate passenger and cargo inspection.

Mr. DURBIN. Is it an answer to part of Miami's problem to suggest to the exporters that they use another facility nearby to have direct contact in the United States?

Dr. KING. As long as we put the experts in place to take care of the Miami overflow, I think that would solve part of the problem.

Mr. DURBIN. So is the problem personnel as opposed to the equipment and space that is being dedicated?

Dr. KING. It is personnel. It is the reason that we would like to increase our spending limitation on the AQI user fee in particular, so that we can put more people into a port like Miami. There are a lot of people working overtime. There is a lot of stress and strain on people to get these flights cleared because they come in at all hours of the day and night.

USER FEE

Mr. DURBIN. Let us talk about that user fee for a second, because there have been complaints primarily from the airline industry about the fact that there is an APHIS user fee that is imposed on each passenger and each aircraft, a little different than any other mode of transportation. In the past, there were complaints that too much money was being collected for the services being rendered. And I think that the Department last year or the year before reduced that fee somewhat.

What is the current status, can you report on whether or not we are accumulating a surplus or can justify the level of the present user fee?

Dr. KING. We reduced the individual airline passengers fee from \$2 to \$1.45, and the aircraft clearance fee from \$76.75 to \$61. So that is one thing that was done. But we have to be very careful of cross-subsidies. In other words, when an aircraft comes in, we inspect passengers and crew members and their baggage, and also the cargo on that plane. And, we inspect the aircraft itself.

So there are really three separate functions and two fees. We have to account for each fee separately and can only use that particular fee or related reserve to finance that function.

We have the ability to obligate up to ten percent above the appropriation limitation on our AQI user fee appropriation. We have now approximately \$69 million in fees that have been collected that are in a special account in Treasury that are not available to us.

Mr. DURBIN. They are not available to you?

Dr. KING. Right now, they are in that special account. We propose that fees collected in the AQI user fee account remain available without appropriation action to better provide services that are driven by demand.

Mr. DURBIN. So these were fees that were collected for inspection purposes, but cannot be spent by your agency?

Dr. KING. Right now, that is correct.

Mr. DURBIN. Who is responsible for that decision?

Dr. KING. I hate to tell you who I think it is.

Mr. DURBIN. You are among friends here.

Mr. SKEEN. You were. [Laughter.]

Dr. KING. It does have to do with the appropriation limitation that is on the AQI user fee program.

Mr. DURBIN. It sounds like Leon Panetta again.

Mr. SKEEN. Or was it the Congress.

Mr. DURBIN. I think that this may be OMB. I am not sure.

Which is it?

Mr. SHEA. No, Mr. Chairman. It is not OMB. It is the annual appropriation, which limits how much we can spend on the program.

Mr. DURBIN. Really, it is our fault?

Mr. SHEA. It was your decision.

Mr. DURBIN. As requested by the agency?

Mr. SHEA. Yes, Mr. Chairman.

FTES AND CONTRACT EMPLOYEES

Mr. DURBIN. Yes. Let the record show that he answered in the affirmative. We have met the enemy, and they are us.

Let me ask you about contract employees. I understand that the USDA is reducing its total number of employees by 7,500.

What do you expect to happen in APHIS over the next five years in terms of FTEs and contract employees?

Dr. KING. We would be looking at a reduction over five years of 455 full-time equivalents. And that means that we have already put into action a plan to make sure that during that five year period of time, we will reach that staff year reduction level.

We are partly doing that by taking advantage of early out and buy out authority. And in October, we will offer buy outs to approximately 130 positions in specific position categories to better target that reduction. We believe that after that happens, given that we are already under a staff year ceiling, we will be able to achieve our staff year reductions through traditional levels of retirement.

How many did you say, 450?

Dr. KING. It is 455.

Mr. DURBIN. It is 455. Let me try to follow the logic here. We are collecting a user fee, so that we can provide the inspection at the airports. We are falling down on the job in Miami, because of lack of personnel. The money that we are collecting is being held in a segregated account. And we anticipate cutting back on employ-

ees. Some of these things do not seem to compute. It just does not strike me that we are going to be able to provide the level of service that we need to provide in some of these airport facilities unless we spend the money in the segregated account, or at least increase the number of personnel who are doing the inspecting.

What am I missing?

Dr. KING. We know that we have to cut back on certain program activities categories. We also are not limiting or not reducing programs that fund AQI inspectors. Because of the importance of that function. It actually leads then to double cutting, or more reductions in other programs that we feel are less important, but certainly are not out there with increasing work loads.

Mr. DURBIN. How many contract employees do we have in your agency?

Dr. KING. For the record. We have about 6,800 full-time and part-time 6,500 employees.

Mr. DURBIN. Pardon me.

Dr. KING. About 6,800 employees in terms of full-time and part-time.

Mr. DURBIN. But in terms of contract employees?

Dr. KING. Oh, contract employees, no.

Mr. DURBIN. Do you know how many?

Dr. KING. I do not know.

Mr. DURBIN. If you could provide it for the record.

Dr. KING. I would be glad to provide for the record.

[The information follows:]

APHIS does not enter personal services contracts for any programmatic or administrative services. In FY 1993, however, there were approximately 300 people that were funded from contracts for services relating to emergency programs, aerial hunting, market cattle inspections, and miscellaneous activities.

AGRICULTURAL QUARANTINE INSPECTION—USER FEES

Mr. DURBIN. Let me return to the fee structure. The airline industry is the only transportation industry which pays two different APHIS fees—a per-passenger fee plus a per-aircraft fee. The per passenger fee is currently \$1.45 and the per aircraft fee is \$61.00.

The steamship/cruise line industry pays only a flat fee for inspection of each vessel and this fee is assessed no more than 15 times per year regardless of how many times a vessel enters our ports.

Why do airlines pay per plane and per passenger APHIS inspection fee, and cruise ships only pay a per vessel fee? Is the nature of the inspection of the passengers and cargo hold different for these two means of conveyance?

Dr. KING. Airlines pay only one fee, the \$61.00 aircraft inspection fee for each arrival of an international commercial aircraft into the United States. The \$1.45 user fee charged for international passenger inspection services is paid for by each passenger, and is merely remitted to APHIS by the airlines. Therefore, the airlines themselves pay only one fee. The \$369.50 vessel user fee covers the cost of all inspection services provided to ships.

The inspection that is conducted for aircraft and cruise ships is essentially the same, however, because aircraft passengers are considered to be higher risk than cruise ship passengers, the intensity of the inspection varies. When inspecting cruise ships, the main ac-

tivities are inspection of the vessel and the crew rather than the passengers. When inspecting aircraft, the main activity involves the inspection of the passengers rather than the aircraft and the crew.

Mr. DURBIN. Last July, the airlines requested a change in the regulations so that the fee collected from the passengers covers all inspections connected with a passenger flight just as the fee collected from the cruise ships covers all inspections. What is the status of this request?

Dr. KING. The Office of General Counsel has advised us that if we were to charge international airline passengers for the cost of providing services to nonpassenger related areas of the aircraft, we would be requiring passengers to pay user fees in excess of the costs of providing services to them. This would be cross subsidizing nonpassenger related aircraft inspection fees, which is contrary to our statutory authorization. However similar to the vessel collections, the airlines could be charged a user fee that would cover the entire cost of clearing international aircraft, including inspection of the passengers and their related baggage. This would substantially increase the cost borne by the airlines.

Mr. DURBIN. At many international airports APHIS inspection has become a bottleneck for inbound passenger processing. What specific steps have APHIS taken to identify risk factors, and determine the number and intensity of baggage inspections required, the amount of personnel and other assets to be allocated, and the circumstances under which APHIS inspection might be waived, for example, in cases of direct connections to outbound international flights?

Dr. KING. APHIS has conducted risk assessments, port reviews, blitzes, and pilot testing to determine the risk factors used to determine the amount and intensity of baggage inspection. Personnel and assets are allocated based upon workload, availability of funds, and personnel ceilings. In order to facilitate passenger processing, APHIS uses x-ray machines, detector dog teams, rover teams, profiling, and selectivity as a basic concept in passenger clearance. APHIS is evaluating a new x-ray technology system referred to as "Automated Baggage Inspection System". This system, if adopted, will allow APHIS to process all baggage much more rapidly. It will take APHIS approximately three years to develop a prototype.

APHIS inspections will be waived when passengers are not entering the country, but transitioning. In addition, no inspection occurs when the passenger remains in an in-transit lounge while awaiting a connecting direct international flight which leaves the United States.

EMERGENCY PEST OUTBREAKS

Mr. DURBIN. Dr. King, each year as if there is a new outbreak of pest or plant disease around the country that calls on the USDA to use its emergency transfer authority to help resolve the problem. The last several years, the fruit fly outbreaks in California have been the best known incidents and last year, I believe, the Asian gypsy moth made the news. More recently an outbreak of Asian gypsy moth occurred on North Carolina, describe for us what has happened the past year in terms of serious outbreaks of pests.

What kind of pest? From where did they come? How have you managed them? What resources did you expend on each?

Dr. KING. Eradication efforts continued in 1993 in California as a result of the fruit fly emergency declared in January 1992. During 1993, increasing numbers of Medflies were captured in 32 locations within Los Angeles, Orange, Riverside, San Bernardino, and San Diego Counties. Also in 1993, new outbreaks of Mexican fruit fly and oriental fruit fly occurred in Los Angeles County. Eradication was declared for the Medfly outbreaks in San Diego and Santa Clara Counties, and Mexican fruit fly outbreak was declared eradicated in early 1993 in the Los Angeles area. An Oriental fruit fly outbreak was eradicated from San Diego County in 1993.

APHIS also continued conducting post-eradication surveys for the Asian gypsy moth in Washington and Oregon. Two years of negative findings are necessary before this pest can be declared eradicated. In addition, in July 1993, the Asian gypsy moth was introduced in North Carolina. APHIS met with Forest Service and State officials to prepare an eradication work plan. Pesticide applications to eradicate this pest began the second week of April 1994. Let me if you please provide a more detailed response for the record.

[The information follows:]

While the exact origin of exotic fruit flies in California is unknown, eradicated areas are increasingly subject to reinfestation due to increased worldwide trade, travel, mail, and cargo shipments. Areas such as the Los Angeles basin are visited by many people from fruit fly infested areas, and residents often travel to and from those infested areas. This makes the region especially subject to the introduction of exotic pests. Hundreds of interceptions of fruit flies during exclusion activities in recent years demonstrates the potential for introduction.

Program response to all exotic fruit fly detections includes high density detection and delimiting surveys, fruit stripping, fruit cutting, and implementation of Federal and State quarantines. Depending upon the type of fruit fly detected, control activities may include the application of pesticides or the release of sterile flies. During 1993, sterile flies were released around areas in which detections occurred.

The Asian Gypsy Moth—AGM—presents a serious economic and environmental threat to the U.S. forests, woodlands, and residential landscapes, with projected losses of \$1 billion over the next 40 years if it becomes established. The female AGM's ability to fly long distances, which the European strain cannot do, complicates strategic management of an eradication program.

On July 4, 1993, a private ocean moving vessel leased to the Military Sealift Command, arrived at Sunny Point, North Carolina. Two days later, a USDA officer observed numerous adult gypsy moths flying around the vessel as the cargo was unloaded. Closer inspection revealed egg masses, pupae, and male and female adult moths on the deck, the superstructure, and in the number three hold. Immediately after the discovery of gypsy moths on the vessel, pheromone traps were deployed in the vicinity of the Sunny Point Terminal and along the Cape Fear River. This trapping resulted in the capture of over 300 moths which were believed to have flown from the ship. Moths taken directly from the ship and captured in these traps were tested for the Asian strain using the nuclear Deoxyribonucleic Acid sequencing process. The results of this testing indicated that 50 percent of the moths were of the European strain, 45 percent were hybrids, and 5 percent pure Asian. The pattern of AGM catches in the detection traps indicates that the moths traveled significant distances from the vessel. Some of the traps containing AGM's were located 30 miles from the Sunny Point Terminal. Trapping activities in these same areas netted only five European strain gypsy moths in 1992.

For AGM, USDA and North Carolina Department of Agriculture officials met and selected an AGM project management team and an AGM science panel. The AGM science panel recommended treatment of approximately 131,000 acres with two or three applications of *Bacillus thuringiensis*—Bt—, a bacteria that attacks lepidoptera (the moth family), and Gypcheck, a virus product. The actual number of applications will be determined by the rate at which the caterpillar hatch this spring, as well as weather conditions during the treatment period. The recommendation also calls for an extensive delimiting survey of the entire area that has the poten-

tial for being infested. This area includes the proposed treatment block and extends approximately 3 miles inland and along the coast, including the Sunny Point Terminal. Two years of survey with negative results following the eradication treatment is required to confirm eradication.

During FY 1993, APHIS provided a total of approximately \$16.1 million in Commodity Credit Corporation funds for the fruit fly eradication program in California and the Asian gypsy moth eradication program in Oregon and Washington. For fruit fly eradication \$13.4 million was transferred with State and local governments in California matching CCC funds with another \$13.4 million. For Asian gypsy moth eradication \$2.7 million was transferred for post-eradication activities in Oregon and Washington.

TROPICAL BONT TICK

Mr. DURBIN. We note that you request a new line item this year—funds for the tropical bont tick. Is this a new pest problem that we have not faced in the past? How do you expect to contain the problem?

Dr. KING. No, the tropical bont tick—TBT—was introduced into the Caribbean in the 19th century on cattle imported to Guadeloupe from Senegal, West Africa. Inter-island spread of the tick is attributed to the cattle egret, which was introduced into the Caribbean in the 1950's. Recent concern regarding the tick is due to the current rate at which the tick is spreading within the Caribbean. It is estimated that at least one island per year will become infested. In addition, reintroductions of the tick into the islands of St. Croix in 1993 and Puerto Rico in 1992 underscore the need for a regional eradication effort. Efforts to eradicate the tropical bont tick from Puerto Rico were initiated in 1992 and are continuing, as part of the cattle tick eradication program, which is funded from a Food and Nutrition Service grant.

APHIS will initiate a pilot project for control of heartwater disease through selective eradication of TBT. A joint European Union—EU—and Caribbean Community—CARICOM—conference held in 1991 recommended a regional program for surveillance and eradication of TBT while it is confined to the Caribbean Islands. The Food and Agriculture Organization of the United Nations—FAO—took the lead in developing a cooperative plan for the eradication of TBT in the Caribbean. The plan envisions a five-year program that includes efforts on the French islands of Martinique, Guadeloupe, and Marie-Galante, and the Dutch island of St. Martin. The French are pursuing eradication independently with Poseidon funds from the EU. Caricom has requested the Inter-American Institute for Cooperation on Agriculture—IICA—to take the lead on starting this project. IICA will begin the surveillance and regulatory phase, and FAO will follow with the eradication phase.

Because current sanitary regulations prohibit the importation of infested animals, and the fact that the distance between Africa and the Caribbean exceeds the flight capabilities of the cattle egret, TBT has a low probability of reintroduction in the Caribbean once it is eradicated.

COMMODITY CREDIT CORPORATION

Mr. DURBIN. How was your emergency authority used in FY 1993? How much did you use for each incidence and was it all transferred from CCC? Have you used your authority in 1994 yet?

Dr. KING. The Secretary's emergency authority was used to authorize the transfer of up to \$25.8 million in CCC funds for eradication of fruit flies in California in FY 1993. Of this authorization, \$13.9 million was transferred and \$11.9 million carried forward into FY 1994.

In FY 1994, \$4.1 million has been authorized to eradicate fruit flies in California. In addition \$4.5 million, has been authorized to eradicate Asian gypsy moths in North California.

USER FEES

Mr. DURBIN. Dr. King, in previous years the Administration has proposed several user fees for APHIS. Does this Administration propose any new user fees for APHIS other than those already authorized? Please explain in some detail any new proposals.

Dr. KING. There are no new proposals for user fees.

Mr. DURBIN. At last year's hearing, Dr. King, you talked about user fees for Import/Export laboratory testing services. You stated that although you had authority for almost three years and that the 93 appropriation assumed you would collect your regulations to collect were still not in place. Where are we with that user fee? Are you collecting now? Did you collect as much as you thought you would in 93? What are the prospects for FY 94?

Dr. KING. On March 22, 1993, we proposed user fees for certain veterinary diagnostic services, including providing certain diagnostic reagents, slide sets, and tissue sets. The fees took effect on September 1, 1993. Funds generated from these fees will be used to recover the costs of testing and producing reagents at the National Veterinary Services Laboratories—NVSL—in Ames, Iowa. Charges are assessed to States, industry, research institutes, universities, importers, exporters, and other Federal agencies requesting services from NVSL.

Generally, fees are charged for diagnostic services other than those done for our animal disease management programs including: laboratory tests to qualify animals or birds for import or export; diagnostic tests on blood and tissue samples referred to APHIS by State animal health officials who require assistance in establishing or confirming a diagnosis (reference assistance); and for certain diagnostic reagents, slide sets, and tissue sets. Diagnostic reagents are biological materials used in diagnostic tests to detect disease agents or antibodies by causing an identifiable reaction.

In FY 1993, we collected \$6.6 million in import/export user fee revenue. This amount is less than we had anticipated because of delayed implementation of the most recent user fees. We collected an additional \$74,000 in veterinary diagnostics user fees in FY 1993, which was a little more than we expected to collect for the one month the fees were in place.

The projected revenue for import/export user fees for FY 1994 is \$6.9 million. This projection would have been higher if the most recent user fee regulations had been in place for the first quarter of FY 1994. These regulations cover the costs associated with supervising and inspecting animals presented for importation into the United States at all entry ports. They also cover embryos and semen, import animal products and byproducts, and a few Animal Import Center—AIC—user fees. We will not see the full effect of

these fees until FY 1995, when they will be in place for the entire fiscal year. We project that we will collect approximately \$1.2 million in veterinary diagnostic user fees for FY 1994, with similar collections in future years.

Mr. DURBIN. You were also looking to establish a user fee to recover costs of providing inspection services at ports-of-entry for all animals and animal products. Is that up and running? What are your fees and collections?

Dr. KING. As of January 21, 1994, user fees cover the costs associated with supervising and inspecting animals presented for importation into the United States at all entry ports. These new regulations also cover embryos and semen, import animal products and byproducts, and a few AIC—Animal Import Center—user fees. However, activities involved in the export of animal products are not covered by user fees. Regulations being proposed to implement fees for the export of animal products and byproducts.

AGRICULTURAL QUARANTINE INSPECTION

Mr. DURBIN. Let's go back to what seems to be the most troublesome of your user fees—the Agricultural Quarantine Inspection Program at the airports. We continue to get complaints from some of the larger airports that passenger and air traffic is delayed because of inadequate staffing by AQI personnel. For the record what did you collect in FY 1993, how many staff years did you use, what did you spend from the user fee account, and what is the balance on hand at the end of the fiscal year?

Dr. KING. For FY 1993, the Agency collected \$100.8 million. However, the revenue amount will most likely increase due to debt management activities and audit findings conducted during FY 1994. In FY 1993, the program used 1,529 staff years and total program costs were \$83.4 million. At the end of FY 1993, the user fee account reserve balance was \$64.9 million.

Mr. DURBIN. How much reserve do you need to maintain to cover personnel benefits?

Dr. KING. When the original user fees were developed, we determined a reasonable balance, or reserve, in the AQI account to be approximately one quarter of our annual operating expenses.

Since the AQI user fee program is very labor intensive, our reserve covers necessary personnel costs to ensure continuity of service in cases of carrier insolvency, bad debt, and fluctuations in activity volumes.

During the FY 1993 rate revision process for the international air passenger, commercial aircraft, and commercial vessel user fee, we re-evaluated the reserve requirements for these fees. Each category must, through user fee receipts, return sufficient funds to APHIS to cover the cost of providing AQI services to that particular category. We determined that our reserve requirement must be based on the collection pattern of each AQI user fee. The reserve is now based on the collection pattern for each fee type, rather than an amount equal to three months operating expenses.

Collections of the international air passenger and commercial aircraft user fees are remitted on a quarterly basis and are due to APHIS 31 days after the end of the calendar quarter. On the other hand, the loaded railroad car user fee is remitted by the railroad

companies 60 days after the month of service. Additionally, the commercial vessel and commercial truck user fees are collected for APHIS by the U.S. Customs Service and forwarded to APHIS monthly. Therefore, the collection patterns of the international air passenger and commercial aircraft user fees dictate a three month operating reserve, the loaded railroad car user fee needs a two month operating reserve, and a one month operating reserve is appropriate for the commercial vessel and commercial truck user fees.

Based on our FY 1995 request of \$101,860,000 for the AQI user fee program, we estimate our reserve need to be \$21.7 million.

Mr. DURBIN. What are the AQI appropriated funds used for that is different than the user fee?

Dr. KING. The AQI appropriation funds certain domestic activities or activities for which a fee could not be reasonably collected. This includes inspection of passengers and aircraft from Hawaii and Puerto Rico and Mexican land border activities, including pedestrian and personal vehicle inspections.

Mr. DURBIN. Can you give me a table that shows by airport the resources for FTEs and funds used in fiscal years 92, 93, and 94. Under your FY 95 budget proposal what would the break down look like?

Dr. KING. See following table.

[The information follows:]

AQI RESOURCES AND FTE'S BY AIRPORT

Location	FY 1992		FY 1993		FY 1994		FY 1995	
	Funds (000)	FTE	Funds (000)	FTE	Funds (000)	FTE	Funds (000)	FTE
Orlando, FL	\$846	9.6	\$868	11.2	\$889	12.8	\$1,795	25.8
Ft. Lauderdale, FL	177	2.3	183	3.0	187	3.1	247	4.1
Tampa, FL	128	2.0	144	3.8	157	2.7	215	3.7
Miami, FL	5,415	108.9	5,755	110.8	5,971	112.4	6,775	126.4
Atlanta, GA	1,004	15.6	1,018	16.1	1,064	18.0	2,175	39.0
Louisville, KY	281	4.3	282	4.5	311	5.0	377	6.0
Nashville, TN	103	1.7	110	1.7	121	1.9	374	6.0
Raleigh, NC	198	1.8	269	3.3	295	4.1	364	6.1
Charlotte, SC	316	3.0	330	5.3	344	6.6	396	7.6
San Juan, PR	3,007	57.8	3,837	65.4	4,396	92.3	4,428	93.0
Mayaguez, PR	222	4.3	245	4.8	342	9.6	357	10.0
U.S., VI	312	6.0	384	6.8	422	8.5	447	9.0
Austin, TX	25	0.6	4	0.1	4	0.1	4	0.1
Brownsville, TX	46	1.2	39	0.1	47	1.2	86	2.2
Corpus Christi, TX	0	0.0	2	0.1	1	0.0	1	0.0
Dallas, TX	1,124	32.0	1,160	30.0	1,261	31.8	1,339	33.8
El Paso, TX	29	1.0	34	1.0	46	1.2	46	1.2
Harlingen, TX	42	1.0	35	1.0	77	1.8	77	1.8
Houston, TX	1,323	34.5	908	29.5	1,340	34.5	1,529	39.5
Laredo, TX	17	0.4	44	1.2	72	1.7	72	1.7
San Antonio, TX	129	2.9	143	3.5	147	3.5	147	3.5

Baton Rouge, LA	6	0.1	6	0.1	6	0.1	6	0.1
New Orleans, LA	315	6.1	226	5.6	239	5.6	239	5.6
Little Rock, AR	12	0.3	10	0.3	11	0.3	11	0.3
Des Moines, IA	4	0.1	4	0.1	4	0.1	4	0.1
Wichita, KS	8	0.2	8	0.2	9	0.2	9	0.2
St. Peters, MO	166	3.9	188	5.4	197	5.2	197	5.2
Lincoln, NE	5	0.1	6	0.2	10	0.2	10	0.2
Bismark, ND	0	0.0	0	0.0	2	0.1	2	0.1
Oklahoma City, OK	14	0.3	11	0.3	5	0.1	5	0.1
Pierre, SD	0	0.0	0	0.0	1	0.0	1	0.0
Albuquerque, NM	2	0.1	3	0.1	14	0.1	16	0.1
Anchorage, AK	376	5.6	393	5.8	389	7.6	441	8.5
Phoenix, AZ	112	1.9	117	1.9	138	2.5	156	2.9
Nogales, AZ	1	0.0	1	0.0	1	0.0	1	0.0
San Luis, AZ	11	0.3	11	0.3	18	0.6	21	0.7
Calexico, CA	12	0.1	13	0.1	11	0.1	12	0.1
Inglewood, CA	4,913	75.5	5,525	95.5	5,800	125	6,577	139.0
Sacramento, CA	1	0.1	1	0.1	19	0.3	21	0.4
San Diego, CA	11	0.3	12	0.3	14	0.3	15	0.4
San Francisco, CA	2,376	46.0	2,559	51.0	2,524	60.8	2,862	67.8
San Jose, CA	73	0.1	101	2.5	144	3.4	163	3.8
Ontario, CA	0	0.0	0	0.0	177	5.3	201	5.9
Denver, Co	95	1.2	100	1.2	130	2.3	147	2.6
Honolulu, HI	5,367	93.0	6,355	134.0	7,435	152.5	8,432	160.1
Hilo, HI	291	5.5	329	7.0	333	7.9	377	8.3

Kahului, HI	601	10.7	1,044	33.9	1,027	35.0	1,165	36.8
Kailua-Kona, HI	357	6.7	509	14.6	500	16.2	567	17.0
Lihue, HI	311	5.7	470	13.9	474	13.6	537	14.3
Billings, MT	1	0.0	1	0.0	19	0.1	22	0.1
Las Vegas, NV	22	0.0	23	0.0	36	0.1	41	0.0
Portland, OR	150	2.4	169	3.2	310	6.9	352	7.7
Salt Lake City, UT	10	0.0	11	0.0	28	0.5	32	0.5
Seattle, WA	564	8.8	610	10.1	623	11.9	706	13.3
Spokane, WA	2	0.1	2	0.1	12	0.3	13	0.3
Cheyenne, WY	1	0.0	1	0.0	3	0.1	3	0.1
JFK, NY	6,379	119.0	7,195	121.0	7,456	120.0	9,237	156.0
Dover AFB, DE	136	3.0	141	3.0	169	3.5	172	3.5
BWI, MD	189	2.0	194	2.0	202	2.0	204	2.0
Andrews AFB, MD	94	1.0	97	1.0	101	1.0	101	1.0
Martinsburg, WV	4	0.1	4	0.1	5	0.1	6	0.1
Norfolk, VA	55	1.0	58	1.0	62	1.0	62	1.0
Dulles IA, VA	405	7.0	422	7.0	436	7.0	780	14.0
Detroit, MI	623	9.3	685	10.0	755	11.0	763	11.0
Airborne Airpark, OH	15	0.3	15	0.3	16	0.3	16	0.3
Cleveland, OH	27	0.6	31	0.6	36	0.7	40	0.8
Dayton IA, OH	20	0.4	21	0.4	22	0.4	22	0.4
Port Columbus, OH	16	0.3	16	0.3	17	0.3	17	0.3
Toledo, OH	6	0.1	5	0.1	7	0.1	8	0.1
Rickenbacker, OH	5	0.1	5	0.1	6	0.1	6	0.1
Wright- Patterson, OH	4	0.1	5	0.1	5	0.1	5	0.1

Bradley IA, CT	52	1.0	55	1.0	61	1.1	63	1.1
Logan IA, MA	561	10.0	584	10.0	603	10.0	611	10.0
Indianapolis, IA	43	0.7	35	0.5	39	0.5	39	0.5
Bangor, ME	160	2.6	127	1.9	177	3.1	197	3.4
O'Hare, IL	1,629	25.0	1,930	30.0	2,147	33.0	2,511	40.0
Philadelphia IA, PA	351	5.0	412	6.0	426	6.0	479	7.0
Pittsburgh, PA	130	2.0	134	2.0	187	3.0	189	3.0
Newark, NJ	1,233	17.3	1,287	17.3	1,417	19.3	2,291	37.0
General Mitchell Field, WI	92	2.0	95	2.0	99	2.0	101	2.0
Twin Cities, MN	158	2.7	163	2.7	173	2.8	187	3.0
Burlington, VT	27	0.6	28	0.6	29	0.6	30	0.6
Newburgh, NY	89	2.0	93	2.0	96	2.0	97	2.0
TOTAL	43,437	781.2	48,450	914.0	52,906	1,049.1	62,849	1,223.4

* The funds listed in the table above include salaries, benefits, and overtime for the corresponding FTE's.

Mr. DURBIN. For the record, please provide a table showing the AQI fee schedule for each activity and changes that have occurred since instituting the user fee.

Dr. KING. See following table.

[The information follows:]

AQI USER FEES

Category	Original fee	Revised fee effective Jan. 1, 1993
Airport operations:		
International passengers ¹	\$2.00	\$1.45
Commercial aircraft ²	76.75	61.00
Maritime operations:		
Commercial vessel ¹	544.00	369.50
Land border operations:		
Commercial truck ¹	2.00	(³)
Loaded railroad cars ¹	7.00	(³)
Phytosanitary certificates:		
Commercial ²	30.00	(³)
Noncommercial and low value ²	19.00	(³)
Reissued ²	6.00	(³)

¹ Fees effective May 13, 1991.

² Fees effective February 9, 1992.

³ No change.

Mr. DURBIN. Do you anticipate any changes in the charges during fiscal year 1994?

Dr. KING. All AQI user fees were reviewed at the end of FY 1993. At this time, we do not plan to propose any changes to these fees during FY 1994.

SALMONELLA ENTERITIDIS

Mr. DURBIN. Last year, we discussed at some length problems related to *Salmonella enteritidis*. How many new occurrences of *Salmonella enteritidis* did you find in 1993 and so far in 1994? How many of the trace-backs have followed to being egg associated.

Dr. KING. During 1993, 62 human outbreaks were reported, compared to 60 in 1992 and 67 in 1991. As of March 15, 1994, no human outbreaks had been reported. This compares to eight during the same period last year. We are continuing to monitor human outbreaks and conduct tracebacks to flocks of origin.

Tracebacks indicated there were 13 egg associated outbreaks in 1991, 26 in 1992, and 21 in 1993 out of approximately 180 billion table eggs consumed during the 3-year period. Since the program began in 1990, 82 (33 percent) of the 249 outbreaks in humans that have been investigated have been found to be egg related.

Mr. DURBIN. Have you made any progress in developing diagnostic tools and control methods for *Salmonella enteritidis*? How is the voluntary programs in the high incidence areas working?

Dr. KING. Yes, we have. The SE pilot project in Pennsylvania has identified key facts that will help develop new methods for controlling SE in egg-layer flocks. Among these are that routine culture of eggs from an SE-affected flock can be used to determine SE risk for humans; that SE vaccine may reduce the number of SE-contaminated eggs in an SE positive flock; that SE in a flock does not appreciably affect the flock's mortality, morbidity, or egg produc-

tion; and that rodents play a prominent role in SE transmission among flocks. We have also carried out studies to determine the feasibility of culturing eggs as a means of detecting SE.

Currently, we are continuing to evaluate information about the role of mice as possible carriers, reservoirs, and amplifiers of SE in hen houses. This may clarify many problems concerning the persistence of SE in these houses. The use of a licensed SE vaccine may act as another tool for SE prevention or reduction in egg-layer flocks.

We consider participation in this type of program to be in the best interest of producers since it helps them control and reduce SE in their flocks and prevents outbreak situations. The Pennsylvania Pilot Project demonstrated that SE occurrence in eggs in Pennsylvania is extremely rare and no flock in the project has been involved in a traceback from an SE outbreak. Also, this pilot project developed a Pennsylvania Egg Quality Assurance Program, which covers an estimated 200 flocks with 12 million birds. This program should contribute significantly to preventing SE cases and outbreaks caused by fresh shell eggs.

PEST AND DISEASE EXCLUSION ACTIVITIES

Mr. DURBIN. For the record, would you please provide a list of the countries and the specific activities in which you have pre-clearance programs for Pest and Disease Exclusion Activities. Also, provide the cost of operating each pre-clearance site in fiscal year 1993 and 1994.

Dr. KING. I will provide a chart which provides countries and commodities involved with pre-clearance programs. There are no costs to the United States since pre-clearance program are operated under Cooperative Trust Fund Agreements with the individual producer. Under these agreements, all costs, such as travel, per diem, and salaries for pre-clearance are paid for by the cooperator.

[The information follows:]

Country	Produce
Argentina	apples, pears, grapes
Australia	apples, pears
Belgium	flower bulbs
Brazil	mangoes
Chile	fruits, vegetables, cut flowers
Costa Rica	papayas
Dominican Republic	fruits, vegetables, herbs
Ecuador	honeydew melons, mangoes
France	apples
Guatemala	mangoes
Haiti	mangoes
Jamaica	fruits, vegetables, cut flowers
Japan	sandpears, unshu oranges
Korea	sandpears
Mexico	citrus, mangoes, stonefruits
Netherlands	bulbs, nursery stock
New Zealand	apples, pears
Peru	mangoes
Spain	clementines, lemons
Taiwan	mangoes
United Kingdom	bulbs
Venezuela	mangoes

PSEUDORABIES

Mr. DURBIN. Currently there is a pseudorabies effort going on in all 50 States. For the record, please provide us a list showing the amounts expended on this program in each of the States and the amount of any cost-share provided by each State. Also, show the stage of each State.

Dr. KING. See following table.

[The information follows:]

FY 1993 PSEUDORABIES EXPENDITURES		
STATE	FEDERAL DOLLARS (Actual) ¹	NON-FEDERAL DOLLARS (Actual)
ALABAMA	\$20,849	\$50,000
ALASKA	684	5,500
ARIZONA	2,704	2,000
ARKANSAS	20,466	20,217
CALIFORNIA	20,785	209,271
COLORADO	78,286	50,000
CONNECTICUT	293	12,313
DELAWARE	2,368	7,500
FLORIDA	100,004	0
GEORGIA	56,169	507,760
HAWAII	2,722	80,797
IDAHO	4,025	0
ILLINOIS	152,102	1,811,923
INDIANA	94,740	1,000,000
IOWA	938,059	2,755,559
KANSAS	33,294	18,472
KENTUCKY	115,374	104,922
LOUISIANA	9,705	0
MAINE	1,049	27,000
MARYLAND	357,106	152,976

¹ Dollar amounts in this column reflect only eradication and control activities. All monitoring and surveillance activities are reflected under our new Animal Health Monitoring and Surveillance line item.

MASSACHUSETTS	4,570	28,413
MICHIGAN	83,494	344,278
MINNESOTA	319,365	519,425
MISSISSIPPI	19,671	32,681
MISSOURI	49,686	90,396
MONTANA	8,970	10,797
NEBRASKA	150,321	635,697
NEVADA	2,787	6,638
NEW HAMPSHIRE	313	2,448
NEW JERSEY	11,949	8,000
NEW MEXICO	2,583	0
NEW YORK	77,955	5,000
NORTH CAROLINA	246,208	2,194,461
NORTH DAKOTA	9,570	7,500
OHIO	81,133	840,219
OKLAHOMA	42,930	243,100
OREGON	2,826	0
PENNSYLVANIA	78,036	520,891
RHODE ISLAND	1,871	0
SOUTH CAROLINA	29,436	190,000
SOUTH DAKOTA	57,023	174,089
TENNESSEE	101,922	206,937
TEXAS	70,787	276,018
UTAH	3,168	8,000
VERMONT	570	0
VIRGINIA	31,606	194,216
WASHINGTON	8,691	15,000
WEST VIRGINIA	4,671	10,000
WISCONSIN	75,456	630,386

WYOMING	6,652	3,000
WASHINGTON, DC	60,416	0
PUERTO RICO	22,626	0
TOTAL	\$3,678,046	\$14,013,800

The States enrolled in the program and the Stage of each as of April 1, 1994 are as follows:

Stage I	Stage II	Stage II/III	Stage III	Stage IV	Stage V
Florida	Illinois	Indiana	Alabama	Montana	Alaska
Iowa	Kansas	Michigan	Arkansas	Idaho	Arizona
New Jersey	Maryland	Minnesota	California	Nevada	Connecticut
Rhode Island	Massachusetts	Nebraska	Colorado	North Dakota	Maine
	Missouri	North Carolina	Delaware	Oregon	Mississippi
	Pennsylvania		Georgia	Washington	New Mexico
	Puerto Rico		Hawaii		New York
	South Dakota		Kentucky		Utah
	U.S. Virgin Islands		Louisiana		Wyoming
			New Hampshire		
			Ohio		
			Oklahoma		
			South Carolina		
			Tennessee		

			Texas		
			Vermont		
			Virginia		
			West Virginia		
			Wisconsin		

Mr. DURBIN. Last year you stated there was a comprehensive cost/benefit study that would be complete in November of 1993. Was the study completed on time? What did the study cost?

Dr. KING. No. In FY 1993, APHIS contracted for this study from Ohio State University's—OSU—veterinary medical schools. Although OSU is still collecting economic data to finalize their study, they did submit a basic productivity and profitability model report in November 1993. The full report should be completed by the fall of FY 1994.

The study will cost approximately \$75,000.

Mr. DURBIN. Based on the results of that study are you able to determine the annual cost to producers from pseudorabies problems.

Dr. KING. We do not yet have results from this study.

Mr. DURBIN. The pseudorabies eradication program was originally a planned ten-year effort. Obviously, because of fiscal constraints, funds have not been available to reach that goal. Have producers offered to accelerate their share of funds to shorten the time frame to eradicate pseudorabies?

Dr. KING. The current funding level for the pseudorabies eradication program combined with additional contributions by pork producers will enable us to eradicate pseudorabies from domestic hogs by the year 2000 in every State except Iowa. Producers in that State have reached their requirements for Federal resources on one occasion. We had planned to provide herd owners with supplemental purchase of vaccines. But the Iowa pork producers recognized Federal fiscal restraints and voted to pay for their own vaccine. Even with this additional contribution from Iowa, though, it remains questionable whether we will be able to maintain the 10-year timetable for that State.

IMPORT/EXPORT INSPECTION PROGRAM

Mr. DURBIN. For the record, please provide a table showing the expenses of the Import-Export Inspection Program, broken out by activity, for fiscal years 1993 and 1994. For each category, how much do you expect to recoup in user fees.

Dr. KING. We will provide two charts that will give a comprehensive picture of activities in the Import-Export Inspection Program. One will show appropriated activities and expenses and the other will show activities, expenses, and revenues for which we are reimbursed.

[The information follows:]

IMPORT-EXPORT APPROPRIATED ACTIVITIES & EXPENSES (Dollars in Thousands)		
APPROPRIATED ACTIVITY	FY 1993 Expenses (act.)	FY 1994 Expenses (est.)
Import: inspect animals at entry ports; inspect zoos, slaughter plants, & rest facilities; etc. ¹	\$ 4,063	\$1,312
Export: endorse Health Certificates, service farms of origin for export shipments, inspect embryo transfer facilities, inspect animals, etc.	1,401	371
National Center for Import & Export--NCIE-- ²	3,337	3,669
Animal Products & Commercial Bird Activities	2,022	1,170
Maintain Truman animal import center during downtime & accommodate illegally imported birds	341	278
TOTAL, APPROPRIATED	\$11,164	\$6,800

¹ These are the major activities that were supported by appropriations in FY 1993, but as of January 21, 1994, they are covered by user fees. Therefore, the FY 1994 figure includes expenses for these activities accrued between October 1, 1993 and January 21, 1994, as well as expenses for other activities. The new regulations cover the costs associated with supervising and inspecting animals presented for importation into the United States at all entry ports. These new regulations also cover embryos and semen, import animal products and byproducts, and a few more Animal Import Center user fees. Field import activities that are currently covered by appropriations include inspections of vessels and pre-entry piroplasmosis screening.

² NCIE operations consist primarily of providing information, advising, and consulting with industry groups, the public, and other governments; conducting risk assessments; export product certification; and developing and implementing standards, regulations, and policies. This work prevents animal disease introduction from imported animals or animal products and ensures that animals offered by the United States for export meet the criteria of the importing country.

IMPORT/EXPORT ACTIVITIES EXPENSES & REVENUES ³ (Dollars in Thousands)				
USER FUNDED CATEGORY	FY 1993 ACTUAL		FY 1994 ESTIMATED	
	EXPENSES	REVENUES	EXPENSES	REVENUES
Harry S Truman Animal Import Center	\$1,500	\$1,203	\$1,469	\$1,469
Other Animal Import Centers ⁴	2,716	2,627	2,583	2,391
Pet, Smuggled, & Commercial Birds	1,778	1,495	1,673	1,304
Reimbursable Overtime	1,468	1,468	1,381	1,381
Export Certification	1,844	817	1,889	701
Import Inspection, etc. ⁵	N/A	N/A	1,889	1,165
TOTAL, USER FUNDED	\$9,306	\$7,610	\$10,884	\$8,411

³ Includes expenses and revenues for user fees, trust funds, and other reimbursable activities. If expenses exceed revenues, the resulting shortfall would be covered by appropriated funds.

⁴ Includes expenses and revenues animal import centers funded through user fees.

⁵ Since these fees were not implemented until January 1994, the revenue generated in future years will likely be closer to costs.

FOREIGN AFFAIRS ADMINISTRATIVE SUPPORT SERVICES PROGRAM

Mr. DURBIN. For the record, provide a six-year table showing the APHIS expenses related to the Foreign Affairs Administrative Support Services Program administrated by the Department of State.

Dr. KING. A 6-year table for FAAS costs will be provided for the record.

[The information follows:]

<i>Fiscal year</i>	<i>Amount</i>
1989	\$452,000
1990	814,370
1991	675,179
1992	802,080
1993	1,031,600
1994 Est.	1,225,641

Mr. DURBIN. Last year you stated that the State Department charges increased by 31 percent in 1992 and 39 percent in 1993. What is the increase for FY 1994?

Dr. KING. Percentages of increases are based on estimated charges provided by the State Department. The actual increase for FY 1992 was 18.8 percent, and the increase for FY 1993 was 28.6 percent. The increase for FAAS costs in FY 1994 is anticipated to be 18.8 percent.

Mr. DURBIN. Have your services increased in any way? Do you have any recourse to pay these charges? Do you think they are fair and reasonable?

Dr. KING. APHIS is not receiving an increase of services from the State Department. On the contrary, due to budget restrictions, APHIS has reduced the number of personnel in the field, thus decreasing the amount of FAAS services required.

APHIS must gain permission from the State Department to place personnel in a foreign location. As part of this process, the Agency agrees to pay for FAAS services. While each location subject to FAAS charges does complete an annual check-list of the services which they will require, there are minimum services for which the Agency must pay.

Because FAAS costs increase despite reduced services, APHIS does not believe these costs to be fair and reasonable.

ELECTRONIC BAGGAGE EQUIPMENT

Mr. DURBIN. For the record, please provide a table showing all the airports in which APHIS uses electronic baggage inspection equipment, the passenger volume, and the amount of equipment located at each of those airports.

Dr. KING. See following table.

[The information follows:]

Electronic Baggage Inspection Equipment

<u>Location</u>	<u>Number of Passengers</u>	<u>Equipment Units</u>
Atlanta, GA	1,097,198	1
Boston, MA	1,142,716	1
Chicago, IL	2,132,036	2
Dallas, TX	1,385,496	1
Dulles, Wash., DC	1,218,797	1
Elizabeth, NJ *	1,350,663	2
Honolulu, HI	2,614,239	21
Houston, TX	1,371,277	2
Jamaica, NY (JFK)	6,930,872	4
Maui, HI	779,000	5
Kailua Kona, HI	123,000	2
Kauai, HI	78,000	2
Los Angeles, CA	6,154,562	4
Miami, FL	6,555,609	3
Orlando, FL	1,041,325	1
San Francisco, CA	2,265,785	2
San Jose, CA	92,231	1
San Juan, PR	1,345,609	13
San Ysidro, CA *	126,126	2
Seattle-Tacoma, WA	456,597	1
TOTAL	38,261,138	71

* In Elizabeth, NJ, one machine is at the post office and the two machines in San Ysidro, CA are at the Mexican border.

ANIMAL IMPORT CENTERS

Mr. DURBIN. For the record, please update the five-year table that appears on page 351 of last year's hearing volume, which shows the number of days occupied and the operating cost for each of the Animal Import Centers. How much was received in user fees for each facility?

Dr. KING. A table illustrating the number of days each animal import center was occupied will be provided.

[The information follows:]

NUMBER OF DAYS OCCUPIED FY 1989-93					
AIC	1989	1990	1991	1992	1993
Newburg	365	365	365	366	365
Miami	365	365	365	366	365
Hawaii	365	365	365	366	365
H S Truman	180	30	90	180	112
TOTAL	1,275	1,125	1,185	1,278	1,207

Annual operating costs and the revenue over the last 5 years for each AIC are shown in the following table:

AIC OPERATING COSTS & REVENUE FY 1989-93 (\$000)										
	FY 1989		FY 1990		FY 1991		FY 1992		FY 1993	
Facility	Cost	Revenue	Cost	Revenue	Cost	Revenue	Cost	Revenue	Cost	Revenue
Newburg	\$1,053	\$1,089	\$968	\$709	\$847	\$839	\$1,409	\$1,673	\$1,520	\$1,748
Miami	412	467	315	266	298	217	816	326	969	621
Hawaii	88	158	204	72	135	141	160	53	227	258
Truman	1,482	1,011	228	0	874	929	1,073	753	1,500	1,203
TOTAL	\$3,035	\$2,725	\$1,715	\$1,047	\$2,154	\$2,126	\$3,458	\$2,805	\$4,216	\$3,830

HARRY S. TRUMAN FACILITY

Mr. DURBIN. Last year you were in the process of revising your rules and regulations for the use of the Harry S. Truman facility in hopes that it could be used more efficiently. What is the status of those changes and what has happened at the Key West facility?

Dr. KING. In July 1993, we proposed regulations to allow more efficient and frequent use of this high-security quarantine facility. The proposed rule will deduct expenses incurred for maintaining the center from the time the lottery winner receives the written offer from APHIS to use the center until the time the importer enters into a cooperative agreement with the USDA for the importation. Small importers would be able to compete fairly with larger importers, since the larger importers would have to submit a separate deposit with each application. The Final Rule docket is under review. We hope to have the rule effective by August 31, 1994.

In addition to the proposed new regulations, we are exploring alternative uses for HSTAIC, such as options for short-term 30- or 40-day quarantines when the facility is not in use for an FMD quarantine.

ANIMAL IMPORT CENTERS

Mr. DURBIN. For the record, please provide us a list of the types of animals that were processed through each of the import facilities during fiscal year 1993.

Dr. KING. A list of the types of animals that are processed through the Animal Import Centers will be submitted.

[The information follows:]

Hawaii Animal Import Center accommodates imports of horses, sheep, goats, birds, and juvenile camelids.

Miami Animal Import Center accommodates birds, ruminants, swine, horses, and camelids

New York Animal Import Center accommodates birds, ruminants, swine, llamas, alpacas, and zoo animals.

Harry S Truman Animal Import Center accommodates ruminants, swine, llamas, alpacas, and birds only from those countries affected with exotic animal diseases.

MEDITERRANEAN FRUIT FLY ERADICATION

Mr. DURBIN. APHIS was cooperating with the Agricultural Research Service in a Mediterranean fruit fly eradication project in Kauai, Hawaii. Because of tropical hurricane Iniki and other operational problems it is my understanding that the project is being totally revamped. What is the status of this project?

Dr. KING. The Agricultural Research Service—ARS—is continuing to develop and demonstrate eradication technologies in Kauai, Hawaii. However, ARS has made changes to their research program for FY 1994. At the end of May 1993, ARS ended the test eradication project for which APHIS was charged with providing a minimum of 50 million sterile flies per week, and using \$400,000 for releasing sterile flies on Kauai. ARS has determined that the eradication of Medflies from coffee fields is not operationally feasible using sterile insects alone. As a result they are developing and testing other publicly acceptable eradication technologies such as mass trapping, augmentative parasite releases, and “male only” sterile fly releases, and increasing research on quarantine treat-

ments to replace methyl bromide. ARS estimates an occasional need of up to 10 million sterile flies per week for these projects and development of sterile fly release technology. Since May 1993, APHIS has been providing these flies as needed. However, in March 1994, on the advice of an international team of fruit fly experts, APHIS committed the entire production capability of the Hawaiian rearing facility to the eradication of the Medfly from the Los Angeles Basin. This commitment is for 2 years.

Mr. DURBIN. What resources have you spent on the project in FY 1993, and 1994? Do you have plans to expend resources on this effort in FY 1995?

Dr. KING. A total of approximately \$1.3 million was spent toward the Kauai project in FY 1993. In FY 1994 and FY 1995, support for the ARS program in Hawaii will be limited to the eradication activities in the Los Angeles Basin. APHIS will continue to provide some equipment and technical assistance as needed. Cost for FY 1994 and FY 1995, are estimated to be approximately \$200,000 for each of these years.

MEXICAN FRUIT FLY/MISSION, TEXAS REARING FACILITY

Mr. DURBIN. Last year, you indicated that because of the Mexican effort to eradicate the Mexican fruit fly that you were reconsidering your proposal to expand the Mission, Texas rearing facility. Have all attempts to expand that facility been abandoned? What capacity do you have to fight a severe outbreak if another one occurs in California? What level of operations did you reach during the last outbreak?

Dr. KING. APHIS currently has no plans to permanently expand the Mission, Texas rearing facility. The facility is producing over 40 million sterile Mexican fruit fly pupae per week. With this amount, we are releasing sterile flies in the Tijuana and Baja California Sur areas of Mexico and in the Lower Rio Grande Valley area of Texas to eradicate MFF outbreaks along the United States border. In addition, the sterile fly production level is sufficient—20 million/per week—for release in the current MFF eradication project in Los Angeles, California. Also, Mexico has a sterile fly production plant in operation for Mexican fruit fly eradication in that country, and they are planning construction of a second facility.

Preparation and modifications to the Mission site and facility during the previous outbreak in 1992, enables APHIS to quickly double the capacity of the rearing facility to 80 million sterile pupae per week if the need arises.

At the peak of the 1992 outbreak, APHIS released 36 million sterile flies per week in the Los Angeles area.

Mr. DURBIN. What resources were expended in fiscal year 1993 and what do you anticipate spending in fiscal year 1994 on that project? Is the reduction a reflection of tight budget constraints or can the program sustain the same level of control with less funds?

Dr. KING. APHIS spent approximately \$2,137,000 in FY 1993 to carry out MFF activities on both sides of the U.S.-Mexico border, and for rearing sterile flies in Mission, Texas. APHIS anticipates spending approximately \$2,272,000 toward this effort in FY 1994.

In FY 1994, APHIS received an increase of approximately \$135,000 over the FY 1993 appropriation for the Mexican fruit fly

line item. A program decrease of \$97,000 is requested for FY 1995. A decrease is possible because of a reduced number of MFF detections in the Baja California Sur area in FY 1993, due to successful cooperative efforts under the Mexican national fruit fly plan and eradication program. Because of this progress, APHIS is able to scale back program activities somewhat in this region.

SCREWORM FACILITY

Mr. DURBIN. We have already discussed the problems from screwworms but let's move to related questions. Last year you stated that you had completed a master plan to move the screwworm sterile rearing facility to Panama from Mexico but that the actual move was not imminent because of a lack of funding. We know there has been some discussion that private capital could be found to build this facility. What is the status of finding outside funds to make the move?

Dr. KING. The master plan mentioned last year was the first step in the construction process that defines the scope of work necessary to construct a new facility. The next step will be the architectural design work which will generate blueprints from which the actual facility will be constructed.

APHIS is exploring various funding sources for the new rearing facility. Options include the involvement of private investors through the U.S.-Panama Commission to construct and lease back the facility to the Commission. The President of Panama made land available for the new facility, and approximately \$10 million in Food for Peace Program funds may also be available. Also being explored is the possibility of entering into a long-term lease for the construction of the facility via the U.S.-Panama Screwworm Commission. This option is being researched for legality.

Mr. DURBIN. The existing facility is located near Chiapas, Mexico which has been the area of some sever Mexican strife. Has this in any way upset the operation of the screwworm facility?

Dr. KING. There was no disruption at the rearing facility in Chiapa de Corzo, Mexico, due to the Zapatista movement in southern Mexico. The rearing facility is generally viewed as an employment/training opportunity for unskilled laborers and is not normally the target of civil unrest. Problems occasionally arise when highways are blocked, prohibiting ingress or egress of materials.

Mr. DURBIN. You were doing a cost/benefit analysis of moving the rearing facility to Panama and maintain a barrier, is that analysis complete? What are the results of the study?

Dr. KING. An operating cost analysis of supporting the barrier in Panama from either a rearing facility in Panama or a rearing facility in Mexico was completed. The study, which did not include capital costs of upgrading the facility in Mexico nor costs of constructing a new facility in Panama, concluded that producing 70 million flies per week in Panama would cost \$10.7 million annually, compared with \$14.4 to \$16.4 million annually for rearing and transporting 70 million flies per week from Mexico.

INTRODUCTION OF ACCIDENTAL PESTS

Mr. DURBIN. Last year, Dr. King, you gave us several examples of the cost to American agriculture if certain pests were acciden-

tally introduced into the United States. Could you again, this year, provide us several examples of potential introduction of pests and what those pests would cause in terms of economic losses to American agriculture?

Dr. KING. A recently completed economic impact study indicates that nationwide losses due to the establishment of the Mediterranean fruit fly would be \$1.5 billion annually. Economic impact of the establishment of Mexican fruit fly is estimated at approximately \$1 billion annually.

If Asian gypsy moth became established in the western United States, economic losses to larch could exceed an estimated \$1 billion over 40 years. A current infestation of Asian Gypsy Moth in North Carolina is estimated to cost \$9,398,000 to eradicate.

The Forest Service reports that the estimate of potential losses and increased production costs over the next 30 years due to the effects of the pine shoot beetle is \$742 million.

NATIONAL ANIMAL HEALTH MONITORING SYSTEM PROGRAM

Mr. DURBIN. For the record, please provide a five-year table including fiscal year 1994, showing the annual cost and the FTEs assigned for each year to the National Animal Health Monitoring System Program.

Dr. KING. See following table.

[The information follows:]

COST OF THE NAHMS PROGRAM

[In thousands of dollars]

Fiscal year	Cost	FTE's
1990	2,907	34
1991	4,633	45
1992	4,794	53
1993	4,844	53
1994 (est.)	4,844	53

Mr. DURBIN. How many States are currently participating in the NAHMS Program? Do you anticipate any new States signing up during fiscal year 1994 or fiscal year 1995?

Dr. KING. Thirty-seven States are currently participating in the NAHMS program. These States include over 70 percent of the Nation's swine, dairy, and beef cattle populations. Those States are Alabama, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, Wisconsin, and Wyoming.

Yes, additional States will be joining the NAHMS effort in future years to achieve similar coverage of the cattle on feed and sheep industries, and two primary segments of the poultry industry. NAHMS projects its coverage to include 39 States by the end of FY 1994, with the addition of Arizona and South Dakota, and 45 States are projected in FY 1995, with the addition of Utah, Montana, and North Dakota, South Carolina, and Delaware.

Mr. DURBIN. For the record provide a listing of participating States and the amount contributed by each as a cost sharing partner.

Dr. KING. States contributed personnel and equipment to the National Beef Cow/Calf Health and Productivity Audit, Veterinary Diagnostic Laboratory Reporting System, and NAHMS cooperative agreements with State university researchers. I will submit a table which estimates the amounts contributed by States as NAHMS cost-sharing partners for FY 1993 and 1994.

[The information follows:]

STATE CONTRIBUTIONS IN HOURS		
STATE	FY 1993	FY 1994
Alabama	\$2,739	\$1,369
Arizona	2,938	1,818
California	36,698	7,521
Colorado	12,555	31,672
Florida	1,943	1,320
Georgia	2,641	2,018
Indiana	698	698
Iowa	698	698
Kansas	23,515	21,515
Kentucky	1,396	1,396
Minnesota	698	698
Missouri	11,652	6,175
Nebraska	698	698
New Mexico	698	698
New York	698	698
North Dakota	698	698
Ohio	698	698
Oklahoma	5,429	3,063
Oregon	698	698
Pennsylvania	4,350	----
South Carolina	698	698
South Dakota	698	698
Tennessee	1,694	1,196
Texas	15,030	9,391
Virginia	3,431	2,067
Wisconsin	698	698
Wyoming	698	698
Puerto Rico	698	698
TOTAL	\$135,783	\$100,293

Mr. DURBIN. Please provide a listing of all the projects that are part of the National Animal Health Monitoring System data base.

Dr. KING. I'll be glad to provide that for the record.

[The information follows:]

The NAHMS database includes integrated results and project work primarily from three project areas: national information surveys producing baseline information on major agricultural commodities; risk assessments and situation analyses of emerging animal and public health issues; and continuous monitoring of animal health and disease trends. This comprehensive surveillance system enables NAHMS to support outbreak investigations and rapidly respond to emerging information needs supporting preharvest food safety, public and animal health, domestic agricultural productivity, and U.S. international trade interests.

NAHMS national animal health and productivity projects include the Beef Cow/Calf Health and Productivity Audit; National Dairy Heifer Evaluation Project; National Swine Survey; and national monitoring of chicken layers and broilers in collaboration with the National Poultry Improvement Plan. The National Feedlot Cattle Health and Productivity Monitoring will be implemented in August and will collect data and biologic samples to better understand *E. Coli* 0157:H7, the pathogen responsible for numerous fatal food poisoning outbreaks in Western States throughout 1993-94.

NAHMS risk assessments and situation analyses target and quantify risk from emerging animal health issues, such as *E. Coli* 0157:H7, that impact food safety, public health, productivity, and/or international trade. NAHMS recently completed a study of the role of cattle as a source of *E. Coli* in ground beef, and is completing a follow-up on dairy herds that had been tested previously for *E. Coli* in the 1991-92 National Dairy Heifer Evaluation Project—NDHEP. The NDHEP tested calves on 1,068 farms in 28 States to estimate *E. Coli* prevalence in dairy herds.

NAHMS analyses also include Bovine Spongiform Encephalopathy Quantitative and Qualitative Risk Assessments and emergency preparedness; Risk Assessment of Bovine Tuberculosis through the importation of Mexican cattle and because of the growth of the captive cervidae industry; and risk assessment of the animal and human disease risks of feeding garbage and waste commodities to hogs.

NAHMS collaborates with industry to monitor death loss, disease and health in major commodities on an ongoing basis. Monthly feedlot cattle death loss and cause data identify key issues and information needs to be targeted in a national survey. Conversely, in the national survey, key national issues requiring more intensive proactive monitoring ("preventive medicine") became evident.

NAHMS supports disease surveillance by compiling veterinary diagnostic laboratory results from Tate diagnostic labs in U.S. regions and disseminating interpretive results quarterly.

UNIVERSITY OF ARKANSAS—PINE BLUFF

Mr. DURBIN. Your budget request provides \$200,000 for the University of Arkansas at Pine Bluff to establish a regulatory science Center of Excellence. Exactly what will this center do and how will it help APHIS accomplish its mission. What other Federal agencies are cooperating in this project? How much in funding is the University providing to this program?

Dr. KING. Presently, there is a USDA-supported curriculum at the University of Arkansas-Pine Bluff designed to attract and train well-prepared and ethnically diverse college students in the unique area of regulatory science and risk analysis. Funding for a Center of Excellence would establish a more formal and longer-lasting linkage with this university for the recruitment and development of an ethnically diverse student population in scientific areas directly related to the Agency's mission. This center would not only help APHIS in accomplishing its mission, but would also strengthen all Marketing and Inspection Services agencies' efforts in this arena by providing closer coordination in related activities.

Within USDA, the Agricultural Marketing Service, Federal Grain Inspection Service, Food Safety Inspection Service, and Packers

and Stockyards Administration will collaborate in the center at various levels of participation. In addition, the Food and Drug Administration, Environmental Protection Agency, and the Occupational Safety and Health Administration have all expressed an interest in cooperating with the Center.

Since 1990, the University has provided more than \$400,000 to establish this unique curriculum and attract students to this degree program. It is estimated that the University will contribute over \$100,000 a year to the Center of Excellence in terms of faculty support, educational materials, hardware/software, scholarships, student projects, and intern programs.

Mr. DURBIN. When do you expect it to be fully operational? Once it is up and running will APHIS continue its financial role?

Dr. KING. At this funding level, and if cooperating agencies' requests are approved, the University of Arkansas at Pine Bluff Center of Excellence would be fully operational in FY 1997. APHIS would continue its financial role once the center is up and running.

ANIMAL DAMAGE CONTROL COOPERATIVE FUNDING

Mr. DURBIN. For the record, how many states currently have cooperative agreements with APHIS related to animal damage control? Also, provide a list of the amounts of cost-share provided by each state and the federal share spent.

Dr. KING. APHIS currently has cooperative agreements for ADC control activities with 47 States. Cooperative agreements include any agreement with the State to conduct ADC activities, including those States making in-kind contributions such as office space or equipment. The following table contains the amount of Federal appropriated funds for FY 1994. The amount of non-Federal contributed funding for FY 1994 is incomplete; therefore, we will provide non-Federal funding for FY 1993.

[The information follows:]

	FY 1994 <u>Appropriated</u>	FY 1993 <u>Non-Federal</u>
Alabama	\$108,000	\$25,979
Alaska	50,100	100,246
Arizona	434,384	215,309
Arkansas	249,690	-
California	1,501,097	2,012,992
Colorado	765,524	303,321
Connecticut	8,230	-
Delaware	7,407	-
District of Columbia	3,000	-
Florida	93,500	-
Georgia	96,500	25,838
Hawaii	82,070	563,694
Idaho	900,819	388,377
Illinois	117,050	79,496
Indiana	91,000	21,187
Iowa	74,120	-
Kentucky	76,500	127,188
Louisiana	352,400	29,888
Maine	133,500	76,000
Maryland	89,593	35,032
Massachusetts	77,110	8,868
Michigan	96,000	2,767
Minnesota	242,500	2,652
Mississippi	472,800	296,647
Missouri	111,180	15,195
Montana	987,759	487,573
Nebraska	289,872	181,341
Nevada	791,172	575,470
New Hampshire	182,500	53,686
New Jersey	96,000	357,946
New Mexico	1,175,550	869,852
New York	131,000	18,126
North Carolina	126,500	77,111
North Dakota	748,721	271,115
Ohio	146,000	40,000
Oklahoma/Kansas	816,152	674,424
Oregon	943,788	726,822
Pennsylvania	74,000	-
Rhode Island	6,660	-
South Carolina	104,000	31,602
South Dakota	375,302	953,880
Tennessee	243,500	281,533
Texas	2,267,320	4,755,324
Utah	972,067	757,038
Washington/Guam	504,013	736,941
Wyoming	971,317	633,000
Vermont	50,000	19,858
Virginia	161,500	49,325
West Virginia	88,000	8,887
Wisconsin	518,000	708,286
Total	\$19,004,767	\$17,599,816

NON-LETHAL METHODS CONTROL TECHNIQUES RESEARCH

Mr. DURBIN. For the record, how much was spent on animal damage control research during fiscal years 1993 and 1994, and how much for each of those years was allocated to non-lethal control techniques? For the record, describe the non-lethal research work you have going on.

Dr. KING. See following table.

[The information follows:]

<u>FISCAL YEAR</u>	<u>TOTAL FUNDING</u>	<u>TOTAL NONLETHAL</u>	<u>PERCENT</u>
1993	\$9,552,000	\$5,234,000	55
1994	\$9,681,000	\$5,500,000	57

Several of the major ADC research projects underway include the following:

- Development of immunocontraceptive vaccine technology to help resolve damage problems caused by overpopulation of various wildlife species. Emphasis is presently placed on the development and efficacy testing of vaccines and oral delivery systems for white-tailed deer, wild rodents, and birds.
- Development of electronic systems to repel waterfowl and aquatic mammals. In pilot studies, in-water electro-repellents techniques have successfully been used to repel ducks, geese, Norway rats, and beavers using portable equipment designed with sensors to ensure that the devices only operate when animals are present.
- Continuation of identification and development of bird repellents. Naturally-occurring compounds such as grape flavorant methyl anthranilate are being developed to reduce bird damage to small fruits, grazing by waterfowl on turf, and reducing feeding and loafing by birds in standing and contaminated water. Within the past year, 24 new potential repellents have been identified.
- Determination of the effectiveness of managing cattail-choked wetlands in sunflower-producing areas of the Dakotas to discourage blackbirds from using these areas for nesting and roosting cover.

DENVER WILDLIFE RESEARCH CENTER RELOCATION

Mr. DURBIN. What is the total cost to implement the entire Master Plan for the Ft. Collins Facility? Please break this down by each stage. How much do you currently have on hand to begin work on the Ft. Collins site?

Dr. KING. The total cost for completion of design, site preparation, and construction was estimated in 1990 to be \$37 million in three Phases: Phase I, \$19.1 million; Phase II, 10.0 million; and Phase III, 7.9 million.

To date, a total of \$10.5 million has been appropriated for this project. At this time, sufficient demand for Phase III of the project is not present nor is it expected to be for the foreseeable future. Thus, a revised cost estimate of \$29.1 million has been developed for completion of Phases I and II of the master plan, which would provide facilities to continue ADC's critical animal control methods development.

ANIMAL DAMAGE CONTROL PROJECTS

Mr. DURBIN. For the record, please provide a detailed description and/or status report on each of the following animal damage projects: beaver damage control project conducted in Wisconsin and Mississippi; blackbird control program in North Dakota, South Dakota, Arkansas, and Illinois; guarding dog program; Delta States animal control program; sunflower research program in North Dakota; the Hawaii rodent control program; the cooperative agreement with State of Maine, Department of Fisheries; and the Olympia, Washington research project.

Dr. KING. See the following.

[The information follows:]

- **Beaver Damage Control Project - Wisconsin**

The cooperative program between APHIS and the Wisconsin Department of Natural Resources was initiated to rehabilitate prime Wisconsin trout habitat. In FY 1994, a total of \$140,981 cooperator and APHIS funds have been allocated for this program. The program has been successful in eliminating beaver damage from over 500 miles of trout streams thus far. These streams have been restored to their previous free-flowing condition.

- **Beaver Damage Control Project - Mississippi**

The cooperative program between APHIS, the State of Mississippi, and numerous counties and individual landowners is continuing with APHIS funding of \$100,000. The Cooperative Agreement with the State of Mississippi has been renewed for FY 1994. This project provides assistance with the management of beaver-caused damage to private property, as well as State and county infrastructures.

- **Cooperative agreement with the Maine Department of Inland Fisheries and Wildlife**

The cooperative program with the Maine Department of Inland Fisheries and Wildlife has been renewed and will continue at the same level (\$75,000) in FY 1994 as in FY 1993. The primary species causing damage are white-tailed deer, black bear, coyote, and beaver. APHIS ADC personnel provide technical assistance through workshops, on-site visits, informational leaflets, and the loan of equipment.

- **Olympia, Washington, research project**

APHIS is providing \$514,000 in support of this project in FY 1994. This station conducts research on methods to reduce forestry losses caused by wildlife, currently estimated at \$100 million annually. Forest crops are becoming more valuable because of increased demand for limited resources. The Olympia Station is the only Federal research facility providing data and methodology for managing forest damage caused by rodents and big game on Federal, State, and private lands. The Olympia Station is researching methods to control losses caused by mountain beavers, pocket gophers, and deer. This includes obtaining the data needed for re-registration of baits and repellents. Additional emphasis is being placed on research into non-lethal silvicultural methods for damage management and on barrier methods and candidate odor repellents to protect seedlings or to reduce reinvasion of rodent burrow systems. New office facilities at Olympia have been provided under a cooperative agreement with the Forest Service, and a cooperative substation has been established at Washington State University to facilitate faculty and student participation in this research.

● **Blackbird control program in North Dakota and South Dakota**

FY 1993 operational funding:

Blackbird/Sunflower	\$316,480
Cattail Management	100,000

APHIS responded to 432 requests for assistance in resolving blackbird damage to sunflowers in FY 1993 in North Dakota and 104 requests for assistance in South Dakota. The number of blackbird complaints decreased 30 percent over FY 1992, due in part to weather conditions that were not conducive to sunflower production. The program uses aerial hazing to reduce blackbird damage to sunflowers. This project involves the use of fixed-wing aircraft flying at low levels over sunflower fields to disperse the birds that have come to the fields to feed. During FY 1993, over 2,011 hours were flown hazing birds away from the ripening sunflower fields in the Dakotas.

The objective of the cattail management program is to reduce blackbird roosting habitat near sunflower fields and thus blackbird damage to sunflowers. In 1993, the ADC program treated approximately 2,137 acres of cattails in North Dakota and about 505 acres in South Dakota.

● **Arkansas Blackbird Program**

Efforts will enhance the existing program which assists Arkansas rice farmers in reducing damage to headed rice caused by blackbirds. APHIS is providing \$50,000 toward this effort in FY 1994. These additional funds are being used to replace worn out and depleted equipment and supplies including a pickup truck, broadcast units, propane canons, pyrotechnics, and two-way radios. On-site demonstrations of nonlethal control techniques are continuing at Arkansas rice farms with equipment being loaned to farmers. Research and permit coordination and informational letters to cooperators are also continuing.

● **Illinois Blackbird Program**

Efforts are directed at reducing blackbird/starling damage to crops, livestock, and human health and safety in Southern Illinois. APHIS is funding \$50,000 for this project. We will hire an ADC wildlife biologist (stationed in Illinois) before the summer bird damage season begins. The biologist will assess the type, severity, and time period in which bird damage occurs in crops, and provide information on the use and legality of control methods, habitat manipulation, and scare tactics. Propane canons, pyrotechnics, equipment/supplies, and instruction are being made available to producers. Dairy and feedlot operators are given assistance in reducing blackbird/starling damage and disease control caused by birds. Cities besieged with blackbird/starling roosts are also provided with information and assistance on methods of dispersing roosts.

● Guarding Dog Program

Guarding dog efforts during FY 1994 will continue at the same level (\$250,000) as in FY 1993. ADC personnel will continue to provide information and advice about livestock guarding dogs as an integral part of ADC's technical assistance program. Our regional offices are staffed with specialists who provide current information on the benefits and use of livestock guarding dogs to producers. They respond to numerous requests for information from livestock producers and make presentations at various meetings throughout the year on the benefits and use of guarding dogs. In addition, each of the States in the Western Region has an APHIS employee designated as a guarding dog resource person to facilitate getting information to producers.

● Delta States ADC program

Of the \$275,000 earmarked for the Delta States initiative, \$125,000 is used for APHIS operational work and the remaining \$150,000 is used for research. Continued efforts are being made at reducing bird damage to aquaculture facilities, controlling blackbird roost problems, reducing blackbird damage in grain crops, and controlling other migratory bird problems in the Delta States. The ADC station in Stoneville, Mississippi, conducts control activities toward this end.

● Sunflower Research in North Dakota

The FY 1994 APHIS funding for this research project is \$95,840, and includes evaluation of breeding waterfowl and broods to glyphosphate treatments in wetlands in North Dakota; effects of glyphosphate-induced changes in wetland vegetation on aquatic invertebrate populations and water quality in North Dakota; population dynamics and behavioral responses of ring-necked pheasants and blackbirds to glyphosphate-treated cattail-choked wetlands in southeastern North Dakota; and the use of an avicide (DRC-1339) to control sunflower damage caused by blackbirds.

● Hawaii rodent control program

The FY 1994 APHIS funding for this program is \$239,300. Station staff have conducted extensive field studies to determine the abundance and habitat relationships of the three species of rats in sugarcane fields, conducted a series of laboratory studies to evaluate the efficacy of registered and candidate rodenticides, and collected data to assist in maintaining the availability of registered rodenticides. Work is continuing to define movement patterns and food habits of rats in macadamia nut orchards, evaluate trapping as a nonchemical means of reducing orchard damage, evaluate bait additives for enhancing consumption or increasing toxicity of rodenticides, assess prebaiting treatments to improve the efficacy of rodenticides for reducing rat damage in sugarcane fields, and determine the weathering characteristics of registered zinc phosphide baits to identify possible improvements. Research is being initiated to investigate nonlethal methods such as physical or odor barriers for reducing rat invasion into sugarcane fields and macadamia nut orchards.

ECONOMIC IMPACT OF WILDLIFE LOSSES

Mr. DURBIN. Last year you provided us some statistics on agricultural losses caused by wildlife. Please update us on the economic impact from predator losses.

Dr. KING. Since 1989, ADC has contracted with the National Agricultural Statistics Service—NASS—to determine the extent and magnitude of wildlife damage to agricultural resources.

A 1992 NASS survey indicated that predators killed 106,000 cattle and calves during 1991, which amounted to a \$41.5 million loss to that industry. Coyotes were the largest cause of cattle and calf predator losses, accounting for almost 62 percent of the total loss to predators. Dogs, mountain lions, bears, and wolves accounted for the remainder of the cattle losses. In 1993, NASS estimated that wildlife caused between \$82 to \$100 million in damage to the corn industry. ADC is planning to have NASS update the survey that was conducted in 1989 to determine the extent of wildlife damage in the United States, followed by a survey in 1995 to determine the extent of predation to the sheep and goat industry.

Mr. DURBIN. Do you have any information on what the economic impact is to the consumer?

Dr. KING. While we do not have detailed data on the economic impact to the consumer, it is no doubt substantial. In addition to the direct costs to industry mentioned above which must be passed along to the consumer, there are also indirect costs which include the ranchers' own expenses as a result of prevention of predation. These include such items as intensified animal husbandry, guardian animals, and payments to predator control programs.

Black bears, mountain lions, and occasionally coyotes can present physical hazards to humans. Raccoons and skunks can transmit rabies directly to humans or to domestic animals. The Centers for Disease Control estimates that some 25,000 persons annually in the United States receive rabies prophylaxis after being bitten. Rodents, such as beaver, nutria, and muskrats damage trees, shrubs, and landscaping in urban areas, as well as rural roads, dams, and levees. Bird roosts in urban and suburban areas can present public health hazards or cause damage to buildings, sidewalks, and shrubbery. Bird populations on or near airports may present major hazards to air traffic and passenger safety. Although comprehensive information is not available on such damage, the total costs are believed to be in excess of \$12 billion annually.

LINCOLN UNIVERSITY CENTER OF EXCELLENCE

Mr. DURBIN. We note that you are establishing a Center of Excellence in Wildlife Management of Lincoln University in Jefferson City, Missouri. How much has been spent on this effort so far? How much will Lincoln University contribute to this effort?

Dr. KING. For FY 1994, APHIS has committed \$117,000 toward the Lincoln University Center of Excellence for Wildlife management. The University is contributing \$25,000 this year.

Mr. DURBIN. What other Federal agencies are contributing to this effort and how much?

Dr. KING. The Forest Service is contributing an amount equal to that provided by APHIS. Also, beginning in FY 1995 the Center

will include a Geographic Information Systems component, supported through the Soil Conservation Service. I'll provide a table that shows the proposed funding mix from the present through FY 2000 for major cooperators in the project, which include APHIS, the Forest Service FS, the Soil Conservation Service SCS, and Lincoln University LU.

[The information follows:]

SUPPORT FOR LINCOLN UNIVERSITY CENTER OF EXCELLENCE, FISCAL YEARS 1994-2000

[dollars in thousands]

Agency	1994	1995	1996	1997	1998	1999	2000 on
APHIS	\$117	\$225	\$200	\$157	\$145	\$137	\$85
FS	116	225	200	158	145	138	85
SCS		300	310	320	330	340	(¹)
LU	25	25	25	100	100	140	135
Total	258	775	735	735	720	755	(¹)

¹ To be determined.

Mr. DURBIN. What will the APHIS role be once the project is ongoing?

Dr. KING. As with the Forest Service and Soil Conservation Service, APHIS plans to continue to be a partner with Lincoln University in ensuring high quality educational opportunities in Geographic Information Systems and Wildlife Management, particularly for women and minorities. APHIS plans to continue to support the program at about \$85,000 per annum—teaching staff \$35,000; student stipend support \$30,000; equipment replacement and maintenance \$13,000; travel \$5,000; and, to use Lincoln University's facilities and capabilities for recruitment and education for future specialists, for in-service training programs for extant agency employees, and as a technical resource for the agency.

Mr. DURBIN. How do you expect this to enhance the APHIS Animal Damage Control Program?

Dr. KING. Primary and direct benefits will result from the increased availability of a pool of excellently trained and highly qualified candidates, particularly women and minorities, to assume resource management and wildlife biologist positions in APHIS, the Forest Service, and the Soil Conservation Service. These students will have the special advantage of having geographic information systems training as well as wildlife management as part of their skills development. Because some of the students will be trained under programs such as cooperative education, the students can be hired noncompetitively and moved efficiently into available positions. Primary and direct benefits will also accrue from participation by students in agency activities during their tenure as students at Lincoln University through research activities sponsored by the program, through summer intern and summer hire programs, and through work-study and cooperative education programs. These benefits have already begun with at least nine students being placed in agency work experiences this summer, ranging broadly from ADC research and operational activities to assistance in the preparation of field and laboratory experiments for Lincoln University wildlife management classes.

Additionally, because the agencies will provide subject matter expertise through both classroom training as well as interagency personnel exchanges, there is a unique opportunity to ensure that program curricula include the particular knowledge, skills, and abilities that are sought in resource managers by APHIS, the Forest Service, and the Soil Conservation Service. The agencies will further benefit from the opportunity to use the expertise and facilities developed at Lincoln University for in-service training programs of existing staff, and as a technical resource for consultancies on specific problem or projects. Finally, the agencies will benefit directly by gaining access to a diverse personnel resource that will contribute to the agencies' workforce and cultural diversities, thereby contributing to the richness of the management of natural resources.

Mr. DURBIN. What expertise does Lincoln University currently have in the area of wildlife management? How as it selected as the Center of Excellence?

Dr. KING. Within its Department of Agriculture, Natural Resources, and Home Economics, Lincoln University has committed to the development of a strong area of emphasis in natural resources management, including range, forestry, and wildlife management, and geographic information systems. The present staff includes a range manager (who is pursuing a doctorate in wildlife biology), a Department Chair, also with a strong wildlife background, and a recruitment and retention specialist with a strong wildlife background. The Department is in the process of hiring a forestry specialist.

Lincoln University currently offers undergraduate courses in natural resources that have wildlife management components, including forest and range management, range and pasture improvement, introduction to natural resources management, and introduction to wildlife management. Both Lincoln University and the Soil Conservation Service have provided expertise in geographic information system—GIS, and courses in these areas are now offered, including fundamentals of GIS, introduction to map reading, and fundamentals of remote sensing. Other departments within Lincoln University, including the Psychology Department and the Biology Department, also have expertise of value in developing a strong wildlife management curriculum.

APHIS, the Forest Service, and the Soil Conservation Service, each determined independently that a Center of Excellence for Leadership in Geographic Information Systems and Wildlife Management at Lincoln University would help to meet their program priorities and future agency recruitment needs. The Soil Conservation Service had already established a presence at Lincoln University, and the 1890's Liaison Officer at Lincoln University had already worked extensively with the Forest Service. At the encouragement of the Department, the agencies collaborated with each other and with Lincoln University to develop a single Center of Excellence proposal.

REDUCTIONS IN ADC METHODS DEVELOPMENT

Mr. DURBIN. Your budget justification indicates you will use \$225,000 from your animal damage control methods development program for this effort. You also reduce the overall account by

\$260,000. Considering inflation and other cost adjustment factors this appears to be a rather significant reduction to the ongoing research program. For the record, please provide the details on which research and reregistration work you propose to eliminate or reduce.

Dr. KING. Funds will continue to be used to support a program that focuses on maintaining and improving current methods for controlling damage caused by wildlife and other free-ranging animals and to continue to search for alternative methods. Funding reductions will occur primarily in the small mammal research programs which will eliminate research projects to develop small mammals control methods; study immunocontraception regarding rodents; study mountain beavers in the Northwest; identify rodenticides to protect sugar cane and macadamia nuts in Hawaii; and maintain current rodenticide pesticide registrations.

AQUACULTURE

Mr. DURBIN. Your budget request proposes a new line item for aquaculture. What element of APHIS would carry out this program?

Dr. KING. ADC and Veterinary Services will each carry out a portion of the program.

Mr. DURBIN. Describe why this has become such an important issue? What is the total make up of the industry being impacted? What will APHIS do to assist the industry?

Dr. KING. The U.S. aquaculture industry has surpassed in value of most domestic fruit, vegetable, and nut crops, and is now approximately equal in value to the sheep and rice industries. Aquaculture is currently the fastest growing segment of U.S. agriculture, and provides about 300,000 jobs. However, it is currently handicapped by a number of factors, including: inconsistent status, not completely recognized as an agricultural industry, and historically regulated by State Fish and Game Departments; increasingly severe production losses attributable to a proliferation of fish-eating migratory birds in key aquacultural areas; lack of uniformity in State regulation; lack of access by the industry to sources of capital and governmental services available to other livestock and farming activities and commodities; and a changing and fragmented regulatory atmosphere, both in this country and abroad.

The EU is currently in the process of implementing rules applicable to health and quality control of fish, fishery, and other aquaculture products intended for import by other nations into this large and very important U.S. trading partner. Moreover, over countries and trading blocs either already have legislation in place regarding aquatic animals and plants, or are in the process of developing and implementing such legislation. An increased level of Federal support for the aquaculture industry at this time to more closely approximate that given other segments of U.S. agriculture would enable this varied and dynamic industry to expand its production while at the same time promoting food safety, raising the quality of aquacultural products, and assuring the continued availability of markets for such products abroad.

APHIS will assist the industry in a number of ways. Our Animal Damage Control program will continue to provide technical assist-

ance and direct control to aquaculture producers experiencing depredation problems with wildlife. This includes providing technical information, loaning equipment, making on-site visits to assess wildlife damage, and recommending the issuance of migratory bird depredation permits. The agency's Plant Protection and Quarantine unit will continue to assist the industry through control of noxious aquatic weeds and exclusion activities at ports-of-entry. Our Biotechnology, Biologics, and Environmental Protection unit will continue licensing and regulation of veterinary biological products used to prevent, diagnose, and treat diseases affecting aquatic animal health. Veterinary Services personnel will continue to issue export health certifications for live fish, fish eggs, and other non-mammalian aquatic and aquacultured animals intended for export to other countries, and provide laboratory assistance to the aquaculture industry for special problem cases.

The new funding proposed in our FY 1995 budget request represents a first step toward development of a comprehensive aquaculture program to provide services to the aquaculture industry and improve the overall health and production characteristics of fish. With the funds, APHIS would implement a program to assist the aquaculture industry in the development of bird damage management plans that will help producers while assuring the biological viability of migratory bird species. APHIS wildlife biologists would work in key aquacultural production areas to coordinate bird depredation management activities with the industry, and State and Federal wildlife management agencies, coordinate biological survey data to develop management information, and develop new control methods. Depredation management strategies would be evaluated, developed, and demonstrated through technical assistance programs, or in some cases directly implemented through cooperatively funded programs.

In addition, we would expand APHIS' role in animal health services including export certification, to include aquaculture products. This role would include, for example, negotiating with the EU to develop and implement export certification procedures that reflect scientific criteria, comply with EU specifications, and meet the needs of domestic fish producers; and helping design a joint industry-government program analogous to the National Poultry Improvement Plan for improving domestic aquatic animal health.

BIOCONTROL

Mr. DURBIN. APHIS has, over the years, been increasing its activities related to biocontrol for such pests as leafy spurge and gypsy moth. For the record, please provide us a table showing the funding for all biocontrol projects for fiscal years 1992, 1993, and 1994.

Dr. KING. I'll be glad to provide a table for the record.
[The information follows:]

Funding for Biocontrol Projects
(\\$000)

<u>Project</u>	<u>FY 1992</u>	<u>FY 1993</u>	<u>FY 1994</u>
Alfalfa weevil	\$104	0	0
Colorado potato beetle	468	\$600	\$521
Diffuse & spotted knapweed	513	700	515
European corn borer	462	549	10
Euonymus scale	514	910	615
Institute	730	* 0	987
Leafy spurge	1,800	2,019	1,800
Sweetpotato whitefly (SPW)	** 550	0	0
Cereal leaf beetle	0	260	521
National Biocontrol Program	0	0	733
Subtotal.....	\$5,141	\$5,038	\$5,702
Russian Wheat Aphid (RWA)	2,400	2,400	2,400
SPW line item.....	0	2,583	3,514
Total.....	\$7,541	\$10,021	\$11,616

* Funded from Methods Development line item in FY 1993.

** Includes \$250,000 in contingency funds.

Mr. DURBIN. Describe for us the activities related to each of the biocontrol projects.

Dr. KING. APHIS conducts a number of biological control projects. I will need to submit individual descriptions for the record.

[The information follows:]

National Biological Control Institute--NBCI-- The NBCI was established within APHIS to facilitate implementation of biological control and integrated pest management technology. Its mission is to promote, facilitate, and provide leadership for biological control. NBCI provides technical advice and information; develops and maintains computerized databases and a Bulletin Board System; initiates, coordinates, and monitors projects in cooperation with other agencies and institutions; and identifies and supports the needs of cooperators. The NBCI coordinates biological control of animal and plant pests, develops initiatives, and seeks opportunities to integrate biological control with other appropriate pest management technologies.

National Biocontrol Program New biological control programs are being initiated in FY 1994 including the gypsy moth--GM--, boll weevil--BW--, brown citrus aphid--BCA--, pine shoot beetle--PSB--, Japanese beetle --JB--, and common crupina--CC--. GM will involve the mass production and release of a new exotic parasite in the United States. The BW program will be testing the augmentative use of a larval parasite with inundative releases in cotton. BCA will be involved with the importation and release of exotic parasites for release in Puerto Rico and citrus growing states. The PSB and CC programs will also be involved in the foreign exploration of natural enemies for the importation and release in the United States.

Colorado Potato Beetle--CPB-- APHIS releases biocontrol agents to demonstrate the effectiveness of a biological control-based potato crop management system. The Agency evaluates the economic and environmental benefits of this crop system because of increased pesticide resistance and environmental contamination considerations.

Diffuse and spotted knapweed--DSK-- Through cooperative efforts with scientists in Switzerland and British Columbia, Canada, the Agency has successfully collected and established a field insectary of natural enemies of the diffuse and spotted knapweed. Although difficult to

obtain, the moth, beetle, and seedhead weevil were collected, imported, cleared through quarantine at Mission, Texas, and released to the field. APHIS collected and released five species of biological control agents for knapweeds. A total of 12 species of natural enemies were collected domestically, redistributed, and released in "field insectary sites" location in 14 States.

Leafy spurge--LS-- Leafy spurge is an introduced species that is unpalatable to livestock. Several species of beetles, Aphthona, are now available from sources in Canada for release to control leafy spurge. APHIS collected over 650,000 natural enemies for redistribution to new locations. Insects were released in 15 States. Previous release sites of these beetles now show a significant reduction of leafy spurge.

Cereal Leaf Beetle--CLB-- The CLB has been a major economic pest of small grains in the northeastern U.S. since it was first discovered in Michigan in 1962. This pest was successfully controlled using biological control techniques. The CLB has now spread to the western States and is found in Utah and Idaho and southeastern States without its total natural enemy complex. APHIS has initiated a new program to redistribute all natural enemies to the west and southeast and import new biotypes of the same species of natural enemies that may be more climatically adapted to the south and high altitudes. A total of 25,260 egg parasitoids were released in 11 states in 1993.

European Corn Borer--ECB-- APHIS attempts to reduce populations of the ECB and related stalk borers by using biological control agents. A parasitic wasp (*Trichogramma ostrinae*) has been released by cooperators into study plots to determine the potential impact of this beneficial organism to the corn borer in crop management systems. Evaluation efforts continue by cooperators to determine establishment and efficacy of this natural enemy.

Euonymus Scale Project--ES-- FY 1991 was the first year of a biological control project for ES, a major ornamental pest. Surveys have been initiated in 23 States east of the Mississippi River to gather baseline data, including distribution of ES and existing native natural enemies of ES. Field insectaries to rear natural enemies for future distribution throughout the U.S. are being established in Indiana, Massachusetts, Michigan, New Jersey, Virginia, North Carolina, Tennessee, California, and Oklahoma. A total of 27,000 natural enemies consisting of two predators and two parasitoids were released in 32 States.

Russian Wheat Aphid--RWA-- APHIS coordinates and supports foreign exploration and quarantine activities for natural enemies of RWA. APHIS rears exotic species of parasites and predators of RWA for field releases, research, and cooperator requests. The Agency released over two million parasites and predators against RWA in 1993 in 12 States (Arizona, California, Colorado, Idaho, Kansas, New Mexico, Nevada, Oklahoma, Oregon, Texas, Utah, and Wyoming). This included 7 parasitoid species, 7 coccinellid predators, and 3 fly predators. APHIS assists methods development in evaluating the ecologic and economic impacts of native and exotic natural enemy species on RWA densities in commercial small grain fields in selected States.

Mr. DURBIN. For the record, please provide us any information you have related to cost savings to producers from using biocontrol methods versus herbicides or pesticides.

Dr. KING. APHIS has supported two major biological control programs which are now complete. The biological control of the alfalfa weevil is expected to produce net social benefits with a present value of \$2.2 billion. This amount is equivalent to a perpetual stream of net benefits equal to \$88 million per year measured in 1987 dollars. Net social benefits refers to the difference between estimated market benefits and government program expenditures. The expected cost benefit ratio associated with the biological control program of the alfalfa weevil is 1:87. Consumers of livestock products and alfalfa producers are expected to be the main recipients benefitting from this biological control project. The biological control of the cereal leaf beetle is another successful APHIS program providing an average annual benefit to the U.S. economy of \$105 million, and a cost benefit ratio of 1:11.

Mr. DURBIN. The budget proposes to consolidate the Russian Wheat Aphid program and the Sweet Potato Whitefly program with the biocontrol program. In fiscal year 1994 these three programs had a combined appropriations total of \$11,643,000. The request for fiscal year 1995 is for \$7,754,000. Since your budget justification shows an increase to the biocontrol program, please provide a table showing all the fiscal year 1994 biocontrol projects, the funding each will receive, and how much each will receive in FY 1995.

Dr. KING. I will be glad to provide a table for the record.

[The information follows:]

[Dollars in thousands]

Project	Fiscal year 1994	Fiscal year 1995
Biocontrol line item:		
Colorado potato beetle	\$521	\$421
Diffuse and spotted knapweed	515	415
European corn borer	10	10
Euonymus scale	615	615
Institute (NBCI)	987	987
Leafy spurge	1,800	1,663
Sweet potato whitefly	0	250
Cereal leaf beetle	521	260
Gypsy moth	0	40
Boll weevil	0	0
Brown citrus aphid	0	125
Pine shoot beetle	0	128
Japanese beetle	0	75
Common crupina	0	32
National Biocontrol Program	733	733
Subtotal	5,702	5,754
Russian wheat aphid line item	2,400	2,000
Sweet potato whitefly line item	3,514	0
Total	11,616	7,754

BOLL WEEVIL

Mr. DURBIN. The boll weevil eradication program expanded into several new areas during fiscal year 1993. Do you expect any expansion in fiscal year 1994?

Dr. KING. The program plans to expand to Northern Alabama, Middle Tennessee, and Eastern Mississippi in 1994.

Mr. DURBIN. Have any States recently passed an amendment referendum for the boll weevil program? Do you expect any States to pass referenda in fiscal year 1995?

Dr. KING. In FY 1993, growers in areas of Alabama, Mississippi, Tennessee, and Texas passed referenda to start a boll weevil program.

Growers in the lower Rio Grande Valley, Texas, voted this year; results from referenda are still unknown. In fiscal year 1995, the Agency expects growers to conduct referenda in the hill section of Mississippi, the adjoining southwest areas of Tennessee, and the Saint Lawrence area of west Texas. In addition, grower referenda might be held late in 1995 in Arkansas, Louisiana, the Gulf coast area, and the central Rolling Plains area of Texas.

Mr. DURBIN. What will be the additional cost to the boll weevil program to fully implement these new States in fiscal year 1994 and 1995?

Dr. KING. Under the accelerated program expansion proposed by the cotton industry, APHIS would need to increase boll weevil funding for FY 1995 by \$22.9 million. A preliminary estimate shows the total Federal cost of a national boll weevil eradication program would be approximately \$426 million over a 7-year period. This would be a rapid expansion of the program which would be comprised of 14 geographic increments. Annual Federal costs would average \$60.9 million per year, ranging from a low of \$28 to a high of \$96 million in a given year, depending on the number of active program increments.

Mr. DURBIN. In the past it has been said that a 1989 Economic Research Service report indicated that the eradication program produced a \$34.00 per acre increase in cotton yields and annual cost savings of about \$30.00 per acre from using less pesticides. Do you have any updates on additional cost savings related to the boll weevil eradication effort?

Dr. KING. The last economic study was done in 1992. This study, which used Georgia as the model, indicated that the eradication program produced \$85-\$100 per acre increase in cotton yields and \$65 annual cost savings from using less pesticide.

Mr. DURBIN. Last year I made a visit to California and was told by some producers that the pink bollworm program has saved about 100,000,000 pounds of pesticide from being applied. Do you have any statistics like this related to the boll weevil program?

Dr. KING. A pesticide application reduction between 40 percent to 90 percent resulted from boll weevil eradication. After accomplishing boll weevil eradication, limited pesticide application is necessary in the eradicated areas to control secondary cotton pests.

Mr. DURBIN. What are the annual damage costs to the producer from boll weevil? Do you have any estimates of how this translates to cost to the consumer or how this effects our producers ability to compete overseas?

Dr. KING. In the States that are not participating in the program, the industry estimates the annual damage cost from boll weevil to be \$122 million. This estimate includes yield losses and pest control costs.

The increased production costs from boll weevil losses make the U.S. cotton producers poor competitors in the international markets. Once the boll weevil is eradicated, saving from less pesticide applications and increased cotton yield would lower U.S. cotton prices in both domestic and international markets.

Mr. DURBIN. For each of the boll weevil programs, please provide funding levels for fiscal years 1993, 1994, and 1995. Break the funding level down into the different areas—southeast, high plains, etc.

Dr. KING. I'll submit that table for the record.

[The information follows:]

BOLL WEEVIL FUNDING

[Dollars in thousands]

	1993	1994	1995
Central eradication and suppression ¹	\$783	\$846	\$900
Southeast eradication	8,374	11,420	11,224
Southwest eradication	932	960	960
Total	10,089	13,226	13,084

¹ Due to planned program expansion into areas of Arkansas, Louisiana, Oklahoma, and Texas, the High Plains Suppression Program name was changed to Central Eradication and Suppression. This new program name reflects better current and future program activities.

CATTLE FEVER TICKS

Mr. DURBIN. Last year, Dr. King, you said that the goal was to eradicate the cattle fever ticks from Puerto Rico by the end of fiscal year 1998. Has that target date moved any? Do you still anticipate eradication by then?

Dr. KING. We do expect to eradicate cattle fever ticks from Puerto Rico by the end of FY 1998, however, there are uncertainties in conducting an eradication program in Puerto Rico. These uncertainties include the level of support from the Puerto Rican cattle owners and the ability to control illegal cattle movements. We will keep you informed of significant changes as they occur.

Mr. DURBIN. What is the status of the Puerto Rico cattle tick eradication effort? What funds are being expended by APHIS, by FNS, and by the Commonwealth of Puerto Rico for this effort?

Dr. KING. Progress in the Puerto Rico *Boophilus* tick eradication program continues to be made with 64 percent of the bovine premises free of cattle ticks by the end of FY 1993. Thirty-six percent of the total premises with bovines are either still pending treatment or are under treatment and remain to be freed of ticks.

I will provide a table showing funding sources and dollar contributions by APHIS, FNS, and the Commonwealth of Puerto Rico since 1988.

[The information follows:]

Fiscal year	APHIS	FNS	Puerto Rico
1988	\$1,375,530	\$8,538,988	\$1,020,000
1989	1,375,530	9,584,926	1,350,204
1990	1,375,530	9,600,000	1,350,204
1991	1,544,154	10,825,000	1,258,605
1992	1,423,238	10,825,000	1,250,605
1993	1,260,514	10,825,000	1,280,000
1994 (est.)		¹ 12,462,000	1,203,403

Fiscal year	APHIS	FNS	Puerto Rico
1995 (est.)		12,462,000	1,203,000

¹ FNS funds were transferred to APHIS for management and dispersal through a cooperative agreement with the Commonwealth of Puerto Rico for the eradication program. No funds were appropriated to APHIS for the Puerto Rico program in FY 1994.

CITRUS CANKER

Mr. DURBIN. What funds do you anticipate spending on citrus canker during fiscal year 1994? Have there been any recent detections of citrus canker within the United States since January 1992?

Dr. KING. APHIS does not anticipate spending any funds on citrus canker in fiscal year 1994. Since January 1992, there have not been any new detections of citrus canker in the United States. Eradication has been confirmed and the citrus canker program was terminated in January 1994.

GOLDEN NEMATODE

Mr. DURBIN. For the golden nematode program, how much during fiscal year 1993 was spent on regulatory activities and how much was spent on research?

Dr. KING. APHIS spent \$644,000 during fiscal year 1993 for golden nematode, of which \$614,000 were spent on regulatory activities and \$30,000 on research.

Mr. DURBIN. Recently, there was a golden nematode resistant potato developed by the Agricultural Research Service. What has APHIS done to promote growing the nematode resistant potato on Long Island?

Dr. KING. APHIS continues to encourage New York State officials to require growers with exposed properties to adopt a biologically based management program. This program includes crop rotation, cultural practices, and the use of golden nematode resistant potato varieties. This should result in a significantly reduced number of new infestations. In addition, the Agency is also working with Cornell University and New York Extension Service officials to insure the growers are informed of the advantages of planting golden nematode resistant varieties. However, since the resistant varieties do not exist to fill all market niches, growers are not willing to stop growing susceptible varieties entirely.

Mr. DURBIN. Can you give us an estimate of the amount of pesticide savings there are from using nematode resistant varieties of potatoes?

Dr. KING. APHIS and the growers ceased using chemicals for golden nematode treatments in 1985, replacing them with a biologically based management program. Since current levels of infestation are at their lowest since program inception, savings from pesticide applications would be minimal. Under the current level of activity, the golden nematode populations would be reduced below detectable levels, but not immediately eliminated from previously infested areas.

Mr. DURBIN. Your budget suggests that you can do with less funding for the golden nematode program because you will turn a portion of the program over to the State. What will the State do that APHIS is currently doing? Have you prepared a Memorandum of Understanding or other document to assure responsibility?

Dr. KING. APHIS will continue the golden nematode program at the current level of activity, shifting from a control program to a regulatory program. The budget reduction results from the removal of residential and commercially developed properties from the list of actively infested areas. The reduced number of regulated areas results in a reduction in the need for survey regulated potato-growing areas and properties. Survey for areas that are released from the actively infested areas list will be picked up by the State. Since the State is already responsible for surveying non-regulated areas, a Memorandum of Understanding is not necessary. APHIS and the State will continue the cooperative effort to encourage growers to plant resistant varieties.

GRASSHOPPER/MORMON CRICKET

Mr. DURBIN. For the grasshopper and Mormon cricket control program, please provide us a five-year table showing the amount appropriated each year, the amount carried over each year, and the amount actually spent for control activities.

Dr. KING. See the following table.

[The information follows:]

GRASSHOPPER/MORMON CRICKET APPROPRIATION, OBLIGATIONS, AND CARRYOVER

Fiscal year	Appropriation	Obligated for control	Carryover into succeeding year
1993	\$6,350,000	\$912,000	\$13,267,552
1992	8,850,000	1,371,000	16,989,512
1991	8,850,000	1,154,000	13,181,888
1990	¹ 15,529,000	1,922,000	12,396,426
1989	8,850,000	315,000	10,371,140

¹ Includes \$6.8 million supplemental for control on Conservation Reserve Program (CRP) land.

Mr. DURBIN. For fiscal years 1991, 1992, and 1993, please provide a table showing how much of the grasshopper and Mormon cricket funds were spent in each State.

Dr. KING. I'll submit the table for the record.

[The information follows:]

Grasshopper/Mormon Cricket Obligations by State

STATE	FY 1991	FY 1992	FY 1993
ALASKA	\$1,858	\$1,597	\$1,489
ARIZONA	602,285	517,546	482,653
ARKANSAS	0	0	0
CALIFORNIA	351,530	302,071	281,705
COLORADO	567,586	487,729	454,846
IDAHO	1,507,463	1,295,368	1,208,035
KANSAS	35,697	30,675	28,606
MARYLAND	883,467	759,166	707,983
MICHIGAN	20,000	17,186	16,027
MINNESOTA	259,434	222,933	207,902
MISSISSIPPI	42,000	35,091	33,658
MONTANA	1,358,521	1,167,362	1,088,677
NEBRASKA	100,450	86,317	80,498
NEVADA	0	0	0
NEW MEXICO	198,448	170,527	159,030
NEW YORK	170,926	146,877	136,975
NORTH DAKOTA	130,835	112,427	104,847
OKLAHOMA	37,518	32,239	30,066
OREGON	68,398	58,775	54,812
SOUTH DAKOTA	390,319	335,402	312,790
TEXAS	417,819	359,033	334,827
UTAH	319,164	274,259	255,768
WASHINGTON	193,315	186,116	154,917
WYOMING	372,731	320,289	298,695
DIST. OF COLUMBIA	45,382	38,997	36,368
TOTAL	\$8,075,146	\$6,957,982	\$6,471,174

Mr. DURBIN. For fiscal years 1990, 1991, 1992, and 1993, please provide us information on how much of the grasshopper control money was spent on survey funds and how much was on control activities.

Dr. KING. See the following table.

[The information follows:]

GRASSHOPPER/MORMON CRICKET EXPENDITURES

[In thousands of dollars]

Fiscal year	Survey	Control
1993	\$3,179	\$912
1992	3,844	1,371
1991	3,861	1,154
1990	3,530	1,922

INTEGRATED PEST MANAGEMENT

Mr. DURBIN. Please provide a table showing how much has been spent on the IPM project for the past five years.

Dr. KING. See the following table.

[The information follows:]

Grasshopper/Mormon cricket integrated pest management expenditures

[In thousands of dollars]

<i>Fiscal year</i>	<i>Obligations</i>
1993	\$2,380
1992	2,751
1991	3,061
1990	2,853
1989	2,638

Mr. DURBIN. Last year, Dr. King indicated that there were several demonstration projects around the country to show results of the grasshopper IPM program. This was an effort to transfer technology to others and you further said that you expected the technology transfer portion of the program to be complete by 1994. Is that still on target?

Dr. KING. Yes. We anticipate the technology transfer to be completed in September, 1994. This has been a successful program and we will continue to institutionalize elements of the grasshopper IPM technology through personnel and program development.

ASIAN GYPSY MOTH

Mr. DURBIN. There were articles in the media lately that suggested great success from your Asian Gypsy Moth control efforts. Please describe the estimate of damage done annually and what your control efforts have produced.

Dr. KING. Asian gypsy moth—AGM—was detected in fiscal year 1992, and eradicated from the Tacoma, Washington and Portland, Oregon areas by fiscal year 1993. High risk ports and waterways were surveyed in 1992 and the Agency is confident that AGM is not established in the U.S. In addition, APHIS is working with shipping lines and Russian officials to develop protocols to prevent AGM introductions to the U.S.

The AGM presents a serious economic and environmental threat to the U.S. forests, woodlands, and residential landscapes, with

projected losses of \$1 billion over the next 40 years if it becomes established. The female AGM's ability to fly up to 25 miles complicates strategic management of an eradication program. Because of the risk of rapid spread, USDA is conducting an eradication program in the infested areas of North Carolina and planning a national survey of high-risk ports and waterways.

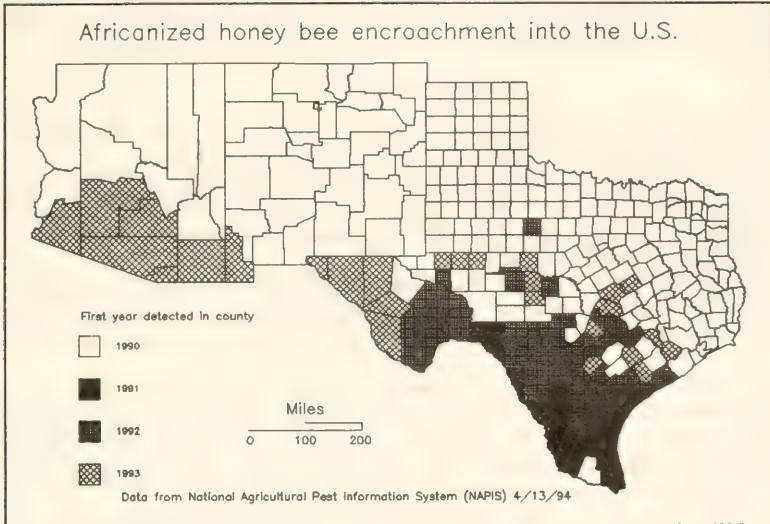
AFRICANIZED HONEY BEE

Mr. DURBIN. Describe for us the extent to which the Africanized honey bee has invaded the United States. What funds is APHIS expending to continue to work on Africanized honey bees in FY 1994?

Dr. KING. I will submit a detailed explanation of our AHB work and a map showing its range for the record.

[The information follows:]

The Africanized honey bee--AHB--entered the United States from Mexico in the Rio Grande Valley in 1990. Since then it has expanded its range into Texas, New Mexico, and Arizona as indicated on the following map.



We have detected AHB aboard ships from South America, Central America, and Mexico at numerous U.S. ports on the Gulf of Mexico and Atlantic coasts. All swarms have been destroyed when detected aboard ships or in port environs.

APHIS plans to spend \$380,000 to maintain existing detection trap lines at ports-of-entry and provide detection survey information for the 1994 swarming season. Also, APHIS will work with the States and Agricultural Research Service in reporting and recording the detection survey results.

APHIS will supply trapping supplies to States for monitoring the spread of the AHB through cooperative agreements. Also, APHIS will supply luminal lenses to States which have a honey bee management plan and are trained to identify the AHB from the European honey bee.

Mr. DURBIN. How much does APHIS expect to spend on monitoring in FY 1995?

Dr. KING. APHIS does not have a specific amount earmarked for AHB in FY 1995. APHIS will coordinate the monitoring of AHB and provide expertise to the States when requested. These activities will be funded by the miscellaneous plant pests program.

IMPORTED FIRE ANT

Mr. DURBIN. For the record, please provide a list of states in which the imported fire ant currently is established.

Dr. KING. Areas in which the imported fire ant is currently established include: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, and Texas.

Mr. DURBIN. Are there any instances where either surveillance or surveys have detected new outbreaks of the fire ant in new states other than those that were established during fiscal year 1992?

Dr. KING. The following States are currently eradicating isolated infestations: California, Nevada, Tennessee, Virginia, and Arizona.

Mr. DURBIN. Please describe for us research efforts that APHIS is conducting in the areas of imported fire ant, including how much is being spent on each project and where.

Dr. KING. In FY 1994, APHIS is spending \$460,000 at its plant methods development station in Gulfport, Mississippi. This facility is the sole source of technology development for support of the Federal fire ant quarantine. This station tests Award and other products annually in a cooperative effort with registrants to develop more cost effective methods of combatting fire ants. The methods development activities include development and refinement of quarantine treatments for certification of regulated articles and advancement of technology for population suppression and control. The Agency provides \$200,000 to the University of Arkansas at Monticello to conduct research on the economic impact of IFA on agriculture and the environment. APHIS works with ARS to screen and develop promising new chemicals and biocontrol agents. In FY 1992 and FY 1993, APHIS worked with States, EPA, and chemical manufacturers to obtain registration for new pesticides, bifenthrin, and tefluthrin.

COOPERATIVE AGREEMENTS

Mr. DURBIN. For the record, please provide us a list that shows the States where you have cooperative agreements, and how much each state is receiving under the cooperative agreement.

Dr. KING. See the following table.

[The information follows:]

Fiscal year 1994 cooperative agreements for imported fire ant

<i>State</i>	<i>APHIS contribution</i>
Alabama	\$147,460
Arkansas	256,700
Arizona	40,000
Florida	170,330
Georgia	81,815
Louisiana	125,000

State	APHIS contribution
Mississippi	91,980
North Carolina	80,790
New Mexico	16,000
Nevada	10,000
Oklahoma	32,000
Tennessee	109,360
Texas	270,000
South Carolina	84,490
California	30,000
Total	1,545,925

Mr. DURBIN. Has APHIS received any request from States for cooperative treatment programs related to the imported fire ant program since 1985?

Dr. KING. No. The Agency has not received any requests from States for cooperative treatment programs since 1985, and many States have proven themselves able to successfully eradicate small isolated infestations outside the regulated area.

MISCELLANEOUS PLANT DISEASES

Mr. DURBIN. For the record, please provide a listing and dollar amounts used to cover specific pests and diseases from the miscellaneous plant and animal account for fiscal year 1992, 1993, and so far in 1994.

Dr. KING. I'll submit that for the record.

[The information follow:]

MISCELLANEOUS PLANT AND ANIMAL DISEASE PROGRAMS

[Dollars in thousands]

Pest/disease	Fiscal year 1992	Fiscal year 1993	Fiscal year 1994
Africanized honey bee	\$308	\$80	\$308
Alfombrilla	3	3	90
Apple ermine moth	85	90	63
Black stem rust	0	0	10
Cherry bark tortrix	75	80	25
Cherry ermine moth	0	0	10
Citrus canker	1,025	1,072	732
Chrysanthemum white rust	180	195	172
Corn cyst nematode	20	22	35
Egyptian cottonworms	7	8	0
European larch canker	35	39	14
Exotic pests	15	0	0
Japanese beetle	235	264	447
Kanal bunt	17	140	0
Khapra beetle	60	68	45
Pea cyst nematode	0	0	45
Poplar rust	0	11	0
Potato beetle	45	50	0
Potato virus Y	844	13	0
Total miscellaneous plant diseases	2,954	2,135	1,996

NOXIOUS WEEDS

Mr. DURBIN. For the record, provide a list of States in which you conduct noxious weed surveys in fiscal years 1992, 1993, and 1994, and tell us which particular pest you are surveying. How much did you spend in each State during those years?

Dr. KING. I'll provide that for the record.

[The information follows:]

NOXIOUS WEED SURVEYS (EXCLUDING OVERHEAD)

State	Pest survey	Fiscal year 1992	Fiscal year 1993	Fiscal year 1994
Georgia	<i>O. minor</i>	\$1,000	\$1,000	\$1,500
Illinois	Herbarium survey	5,500	5,500
New Mexico	Onion weed	1,400	1,900
South Carolina	<i>Cuscuta</i>	2,000	2,000
Texas	<i>O. ramosa</i>	14,500	30,00	26,000
All of the United States	National Herbarium survey	21,167	21,167
Total		45,567	61,567	27,500

Mr. DURBIN. What are you spending in each State on control or eradication work?

Dr. KING. See the following table.

[The information follows:]

NOXIOUS WEED CONTROL (EXCLUDING OVERHEAD)

State	Pest survey	Fiscal year 1992	Fiscal year 1993	Fiscal year 1994
California	<i>Hydrilla</i>	\$100,000	\$100,000	\$100,000
California	<i>Salsola</i>	10,000
Florida	<i>mimosa pigra</i>	26,000	5,000
Georgia	<i>O. minor</i>	4,000	4,000	6,500
Idaho	<i>Crupina</i>	60,000	20,000
Oregon	<i>Crupina</i>	70,000	30,000
South Carolina	<i>Cuscuta</i>	8,000	8,000
Texas	<i>O. ramosa</i>	80,000	124,000	90,000
Utah	<i>Goatsrue</i>	125,000	110,000	100,000
Washington	<i>Crupina</i>	70,000	30,000
Total		543,000	441,000	296,500

Mr. DURBIN. Have you discovered any new noxious weed introductions in the U.S. in the last couple of years?

Dr. KING. In the last couple of years, APHIS has discovered *orobanche minor* in Virginia and Georgia, *thesium* specimens in Montana, *cuscuta japonica* in South Carolina, and *mimosa pigra* and *ipomoea aquatica* in Florida. The Agency conducted eradication activities for *orobanche minor* and control activities for *cuscuta japonica*. In addition, APHIS is monitoring spread of the *thesium* specimens.

Mr. DURBIN. For the record, describe each of the current plants that APHIS is doing control work and describe the potential problems it creates.

[The information follows:]

Goatsrue—perennial weed that competes with and reduces yields of forage plants in moist or irrigated pastures, grasslands, marshy areas, river banks, and roadsides. Goatsrue is mildly toxic to livestock; it contains a poisonous alkaloid, galegin, which lowers the blood pressure and paralyzes the central nervous system.

Hydrilla—annual or perennial aquatic herb that forms dense mats in springs, ponds, lakes, ditches, marshes, paddy fields, slow streams, and others. These dense blockages clog irrigation pumps, inhibit passage, and limit recreational use of waterways.

Orobanche ramosa—obligate parasite (totally dependent upon a host of nutrients) infesting broadleaf plants. This perennial weed competes with and reduces the yields of various crops including tobacco, tomatoes, melons, celery, sunflowers, safflower, carrots, cabbage, eggplant, potatoes, turnips, clovers, and grapes. Heavy infestations can cause total crop failure.

PINK BOLLWORM

Mr. DURBIN. The last several years, Congress provided additional funds to fully equip the Pink Bollworm Sterile Moth Rearing Facility in Phoenix, Arizona. What additional equipment will be purchased in fiscal year 1994.

Dr. KING. APHIS will continue to buy carts to grow sterile moths. The price of these special carts have increased over the past years, making it difficult to estimate the cost for the equipment needed to increase production for further program expansion.

Mr. DURBIN. Is the new facility operating at the level of capacity of the old facility?

Dr. KING. Yes. The old facility was capable of producing up to 4 million moths per day and the new facility is currently producing 5 million sterile moths per day.

Mr. DURBIN. What would be the annual cost of the proposed integrated pest management demonstration project in FY 1995 if funds were available? Is the facility currently equipped to accomplish the demonstration project if the decision were made to move ahead?

Dr. KING. The annual cost would be \$925,000. This estimate includes \$425,000 for the project and \$500,000 of added diet to produce an additional 2 million moths a day for the demonstration project. APHIS would not need to acquire additional equipment to raise production by 2 million moths a day.

Mr. DURBIN. Please provide a table showing the amount of funds provided by cotton producers to operate that facility for each of the past five years.

Dr. KING. See the following table.

[The information follows:]

Producer contributions to operate the pink bollworm rearing facility

<i>Fiscal year</i>	<i>Thousands</i>
1993	\$1,833
1992	1,472
1991	1,835
1990	1,834
1989	1,665

Mr. DURBIN. What is the dollar value loss to cotton annually from pink bollworm problems?

Dr. KING. The pink bollworm is capable of destroying a cotton crop. Losses in the Imperial Valley of California could exceed \$250 million, or about \$300 per acre, each year. The program has prevented infestation and similar losses on over 1 million acres of cotton in the San Joaquin Valley. Also, regulatory efforts have prevented infestation and crop losses on over 3 million acres east of the Mississippi River.

Mr. DURBIN. Of the amount available for pink bollworm each of the past three fiscal years, how much is to be spent on equipment purchases, regulatory and survey activities, and operation of the facility?

Dr. KING. See the following table.

[The information follows:]

PINK BOLLWORM FUNDING

	1992	1993	1994
Regulatory and survey activities	\$799	\$492	\$1,370
Equipment	1,500	1,800	1,000
Operation of facility	500	500	500
Total	2,799	2,792	2,870

BRUCELLOSIS PROGRAM

Mr. DURBIN. The brucellosis program continues to make significant progress. For the record, please provide a list of the States and their status.

Mr. KING. I will provide a table showing the Senate classifications as of March 31, 1994.

[The information follows:]

Class Free: Alaska, Arizona, California, Connecticut, Delaware, District of Columbia, Hawaii, Idaho, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Utah, Vermont, Virgin Islands, Virginia, Washington, West Virginia, Wisconsin, Wyoming.

Class A: Alabama, Arkansas, Colorado, Florida, Georgia, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Nebraska, New Mexico, Oklahoma, South Dakota, Tennessee, Texas.

Mr. DURBIN. How much was spent in each of these States on brucellosis activities in fiscal year 1993 and what are your estimates for 1994 and 1995?

Dr. KING. I will provide a table that shows the amount spent, by State, in the brucellosis eradication program in FY 1993, as well as, estimates for FY 1994 and FY 1995. Monitoring and surveillance activities are funded from the animal health monitoring and surveillance line-item:

[The information follows:]

State	Fiscal year 1993	Fiscal year 1994	Fiscal year 1995
Alabama	\$512,080	\$523,000	\$434,405
Alaska	733	749	622
Arizona	145,158	148,253	123,140
Arkansas	624,713	638,035	529,953
California	874,067	892,706	741,484
Colorado	2,578,914	2,633,908	2,187,731
Connecticut	8,337	8,515	7,072
Delaware	1,485	1,517	1,260
Florida	2,805,926	2,865,761	2,380,309
Georgia	831,849	849,588	705,670
Hawaii	44,041	44,980	37,361
Idaho	289,260	295,428	245,384
Illinois	249,247	254,562	211,440
Indiana	116,863	119,355	99,137
Iowa	653,822	667,765	554,647
Kansas	474,260	484,373	402,322
Kentucky	592,579	605,216	502,694
Louisiana	1,077,853	1,100,838	914,359
Maine	29,447	30,075	24,980
Maryland	3,439,811	3,513,164	2,918,043
Massachusetts	122,409	125,019	103,841
Michigan	165,586	169,117	140,469
Minnesota	1,537,072	1,569,850	1,303,921
Mississippi	950,341	970,607	806,188

State	Fiscal year 1993	Fiscal year 1994	Fiscal year 1995
Missouri	687,925	702,595	583,577
Montana	128,739	131,484	109,211
Nebraska	621,529	634,783	527,252
Nevada	176,483	180,246	149,713
New Hampshire	7,225	7,379	6,129
New Jersey	83,513	85,294	70,845
New Mexico	257,489	262,980	218,432
New York	569,790	581,941	483,361
North Carolina	253,928	259,343	215,411
North Dakota	191,728	195,817	162,646
Ohio	137,236	140,163	116,419
Oklahoma	892,390	911,420	757,028
Oregon	164,248	167,751	139,334
Pennsylvania	336,526	343,702	285,480
Rhode Island	6,016	6,144	5,103
South Carolina	253,634	40,659	199,892
South Dakota	210,038	214,517	178,178
Tennessee	608,525	621,502	516,221
Texas	4,275,739	4,366,918	3,627,173
Utah	203,639	207,982	172,750
Vermont	35,323	36,076	29,965
Virginia	147,760	150,911	125,347
Washington	231,333	236,266	196,243
West Virginia	107,565	109,859	91,249
Wisconsin	510,073	520,950	432,702
Wyoming	343,196	350,515	291,138
District of Columbia	544,546	556,158	461,946
Puerto Rico	262,666	268,267	222,823
Total	30,356,655	31,004,003	25,752,00

Mr. DURBIN. The budget proposes a significant reduction to the brucellosis program in FY 95. What is the current projection for free status for all States and what will it slip to if you get your budget request?

Dr. KING. The FY 1995 President's budget proposes to reduce funding for the brucellosis eradication program by \$5 million. Due to the tremendous success of the program, the Agency feels confident in reducing the program's funding in FY 1995 below the originally planned level. APHIS has made remarkable progress since the initiation of the Rapid Completion Plan—RCP—in FY 1991. As of February 1994, only 229 cattle herds remain under quarantine, as compared to 959 herds under quarantine in FY 1990. This is the lowest incidence of the disease since eradication efforts began 60 years ago. APHIS's goal continues to be eradicating bovine brucellosis, with all States achieving free status by FY 1998.

Mr. DURBIN. What will the cost to the producer be if the target date slips?

Dr. KING. Current estimated annual losses in the dairy and beef cattle industries, due to brucellosis, are at \$10 million. APHIS does not anticipate the target date of FY 1998 slipping as a result of the reduced funding level in FY 1995. However, we anticipate that by FY 1998, only a few herds will remain under quarantine and costs to the producers should be minimal.

Mr. DURBIN. Do you anticipate any States going to Free status during fiscal year 1994?

Dr. KING. So far in FY 1994, one State, California, has been elevated to free status. Another State, Nebraska, has applied for free

status. We anticipate that five other States including Alabama, Tennessee, Iowa, Colorado, and Georgia, will apply for free status in FY 1994. To qualify for free status, the States must be free of brucellosis for one full year.

Mr. DURBIN. Last year you stated that once all states were free it would take about \$34 million annually to provide for monitoring and surveillance to keep the states free. Your budget request will bring you down to a level of \$25,752,000. Can you explain what the USDA commitment is to the eradication effort?

Dr. KING. Consistent with last year's statement, we have included approximately \$32 million in the animal health monitoring and surveillance line-item for brucellosis monitoring and surveillance activities. Surveillance for disease and the complementary monitoring of animal health are long-term commitments to protect and improve animal and human health.

Also, included in the budget is \$25,752,000 for the brucellosis eradication program. APHIS will continue to pursue the goal of eradicating brucellosis at the reduced level. Given the program's recent success, we can remain on target to achieve eradication. APHIS remains strongly committed to eradicating brucellosis from the bovine and swine populations of the United States.

PRE-HARVEST PATHOGEN REDUCTION PROGRAM

Mr. DURBIN. One of your new line item proposals is to establish a preharvest pathogen reduction program. Can you provide an object class table for the request of \$5,702,000?

Dr. KING. The object class table for the request of \$5,702,000 will be provided.

[The information follows:]

<i>MOC and Description</i>		<i>Thousands</i>
11	Personnel compensation	\$2,686
12	Personnel benefits	556
21	Travel	170
22	Transportation of things	114
23	Rent, communications, utilities, and misc. charges	313
24	Printing and reproduction	14
25	Other services	980
26	Supplies and materials	478
31	Equipment	391
Total		5,702

Mr. DURBIN. How much of these funds do you expect to use to redesign of an identification and recordkeeping system?

Dr. KING. The Agency's request includes approximately \$1.5 million for animal identification and trace back. Of this amount, \$300,000 will go towards redesigning an identification and recordkeeping system. The Agency's current animal identification system enables us to trace back certain animals to their premises of origin but does not provide for the identification of all animals. APHIS will collaborate with the Food Safety and Inspection Service—FSIS—and other public health officials to create a more effective identification and recordkeeping system for foodborne disease outbreaks. Such a system will generate fast and accurate identification of the animal's origin and will promote producer confidence and accountability.

Mr. DURBIN. Part of the proposal is to establish a Center of Excellence at the University of Maryland—Eastern Shore. How much will APHIS contribute to its establishment? What will other agencies contribute?

Dr. KING. APHIS has included \$250,000 in the FY 1995 President's budget for the establishment of a food safety Center of Excellence at UMES. Both ARS and FSIS have included an additional \$250,000 in the FY 1995 President's budget.

Mr. DURBIN. What criteria was used to select this University for the food safety Center of Excellence?

Dr. KING. UMES was selected for the food safety Center of Excellence, primarily, because of its ideal location near the geographic center of the Delmarva peninsula, one of the World's greatest regions for poultry production and research. The University's existing strength in this area, their willingness to focus on a topic of interest to the Agency, and their standing as the only 1890 Land Grant Institution on the Delmarva peninsula, were also factors in the selection.

Mr. DURBIN. Are other agencies participating in the preharvest pathogen reduction program? Which ones and to what extent?

Dr. KING. In addition to APHIS, seven other USDA Agencies—FSIS, ARS, CSRS, ERS, ES, FNS, and P&SA—are participating in the preharvest pathogen reduction program. In the FY 1995 President's budget, APHIS, along with FSIS, ARS, CSRS, ERS, and ES, have presented a coordinated proposal for the expansion of this program to deal with the problem of pathogens in meat and poultry food products. I will provide a description of the responsibility for each of the agencies for the record.

[The information follows:]

FSIS—FSIS will identify methods and technology that might be effective in controlling pathogens during animal slaughter and processing of the product; will adapt the new methods and technology to meat and poultry inspection conditions; will test them for effectiveness in field conditions; and will continue its efforts to educate food handles and retailers on proper handling techniques in concert with ES, public health agencies, and the industry.

ARS—ARS will conduct research on effective production systems in concert with academia, industry, APHIS, and ES to expand on the practical aspects of applied technology. Efforts to control bacterial pathogens in poultry, cattle, sheep, and swine will be undertaken, by determining the epidemiology and the pathogenesis of specific pathogens, developing vaccines and other immunity enhancers, and developing rapid methods of identification of carrier animals.

CSRS—CSRS will mobilize the substantial resources of Universities to develop and evaluate new methods of identifying and controlling on farm contamination of animals. This will enhance the efforts of ARS to meet the needs of applied technology.

ERS—ERS will add an economic component to the microbiological baseline data being collected by FSIS by assembling secondary data on the economic costs of foodborne illness and by expanding research on the economic costs and benefits of microbial control options.

ES—ES will expand its preharvest educational programs to assist producers, veterinarians, and researchers in defining and implementing TQM principles and HACCP principles which address ways to minimize animal disease producing microbes in human food products; and will provide consumer and food handler education through the media, publications, newsletters, workshops, and telephone calls.

USDA has also established a Pathogen Reduction and Food Safety Task Force to coordinate efforts to reduce pathogens in meat and poultry. Membership includes representatives from APHIS, AMS, FSIS, P&SA, ES, ARS, FNS, and CSRS. In addition, officials from the Food and Drug Administration—FDA—and the Centers for Disease Control and Protection—CDCP—are participating. The task force is responsible for providing leadership, coordination, and oversight so that the Department's

ongoing efforts to reduce pathogens in the meat and poultry supply are realized in a timely, professional, and scientifically supportable manner.

SWEET POTATO WHITEFLY

Mr. DURBIN. What is the status of sweet potato whitefly activities during fiscal year 1994?

Dr. KING. During FY 1994, the Agency will be conducting surveys to determine the extent of SPW infestation. These surveys should enable APHIS to identify the pest's native natural enemies, establish exotic species, and determine their rate of natural dispersal. Also, APHIS will participate with the Agricultural Research Service—ARS—in an expedited and intensified program to evaluate and implement biological control technology for use against the SPW outbreak.

The goal of the program will be to introduce natural enemies of SPW into the United States that will reduce SPW populations to a point below the economic injury level and eliminate the demand for insecticides. The Agency will also develop capabilities to acquire, mass produce, and release natural enemies. After these insects are released, the Agency will monitor their establishment and rate of natural dispersal, and evaluate the biological and economic impact of their attacks on the SPW.

In addition, APHIS will identify SPW-transmitted plant viruses, assess the biological control program's economic impact, and provide technology transfer on biological control of the SPW. The Agency will also evaluate insect pathogens for their ability to control the SPW and develop mass production systems for SPW as a host for parasites and predators.

Mr. DURBIN. What were the agricultural losses attributed to the sweet potato whitefly in the United States during fiscal year 1993?

Dr. KING. Losses amounted to over \$200 million in 1992 in the Imperial Valley of California, the Colorado River Basin of Arizona, and the Lower Rio Grande Valley of Texas. In 1993, whitefly damage was lower than the previous year in Arizona and California, but yield losses in some melon crops in the Lower Rio Grande Valley reached approximately 66 percent, due to a gemini virus which is vectored by the sweet potato whitefly. Greenhouse losses on ornamentals in 1993 are not yet available.

Mr. DURBIN. Where are you spending research dollars on sweet potato whitefly and how much?

Dr. KING. See the following table.

[The information follows:]

Fiscal year 1994 sweet potato whitefly resources

<i>State</i>	<i>Resources</i>
Alabama	\$8,200
Arizona	¹ 830,000
California	220,000
Connecticut	30,100
Florida	25,000
Georgia	9,000
Mississippi	150,000
New Hampshire	31,600
New Jersey	4,000
New York	29,100
Puerto Rico	29,100
Texas	² 1,481,900

<i>State</i>	<i>Resources</i>
Maryland	508,400
Minnesota	118,200
Washington, DC	39,400
Total	3,514,000

¹ Includes Phoenix Methods Development Laboratory.

² Includes Central Region, Lower Rio Grande Valley Project, rearing and quarantine labs, and cooperative agreements with four States and ARS.

TROPICAL BONT TICK

Mr. DURBIN. The budget requests a new line item of \$537,000 for the tropical bont tick. Describe for the record the significance of an occurrence of this tick into the mainland.

Dr. KING. The Tropical Bont Tick—TBT—was introduced into the Caribbean in 1828 on cattle imported to Guardloupe from Senegal, West Africa. Since being introduced into the eastern Caribbean, the tick has become established on 14 islands and is reported from 19 islands. The spread of TBT is attributed to the inter-island movement of uninspected commodities, livestock, and birds which can transfer immature ticks between islands.

Without an intensive eradication program Venezuela, Florida, and the Yucatan Peninsula of Mexico will eventually become TBT infested. Once this occurs, eradication will be unlikely and both wild animals and domestic livestock will be at risk for heartwater and other associated infections. In addition, there are three other species of ticks endemic to the United States that are capable of spreading heartwater.

The Spread of TBT throughout its potential range in the Western Hemisphere could cost producers up to \$762 million annually. Reduction of meat and milk production could result in losses of up to \$722 million per year, and producers would incur increased costs for tick control totaling approximately \$40 million. Dairy farms would be the most severely affected by the spread of TBT. Reduced production of cow's milk would account for about 85 percent of the decreased value of production, with lower beef output accounting for another 14 percent. Other products such as goat milk and meat, and mutton, would also be affected. The value of domestic livestock inventories in the affected areas exceeded \$37 billion in 1991.

Mr. DURBIN. It is my understanding that the control of this pest is an international project. What other countries are involved and how is the work being coordinated?

Dr. KING. A joint European Community and Caribbean Community conference held in 1991 recommended a regional program for surveillance and eradication of TBT while it is confined to the Caribbean Islands. The Food and Agriculture Organization of the United Nations—FAO—took the lead in developing a cooperative plan for the eradication of TBT in the Caribbean. The plan envisions a five-year program that includes efforts on the French islands of Martinique, Guadeloupe, and Marie-Galante, and the Dutch island of St. Martin. The French are pursuing eradication independently with Poseidon funds from the EU. Caricom has requested the Inter-American Institute for Cooperation on Agriculture—IICA—to take the lead on starting this project. IICA will begin the surveil-

lance and regulatory phase, and FAO will follow the eradication phase.

Mr. DURBIN. What is the current known infestation of this pest in the Western Hemisphere?

Dr. KING. The Tropical Bont Tick is established on 14 islands in the Caribbean and is reported from 5 other islands. No reports of this tick have been received from any other country in the Western Hemisphere.

BOVINE TUBERCULOSIS

Mr. DURBIN. What are the estimated losses to the cattle industry each year from tuberculosis?

Dr. KING. In recent years, we have been able to hold tuberculosis outbreaks down to about 10 or less per year. However, during the past 3 years the incidence of tuberculosis lesions in imported Mexican steers has increased significantly and exposure of cattle to infected domesticated deer and elk has also increased. Tuberculosis outbreaks cause losses to herd owners through the inability to move and sell animals, loss of milk production, calf weaning weight loss, livestock devaluation, revenue loss, and debt restructuring. The owner may also experience losses when replacing exposed or reactor cattle. This is particularly true for dairy cattle owners. For example, a herd owner whose dairy animal valued at \$2,000 is found to be a TB reactor, would be reimbursed only \$1,000, which includes APHIS' payment of \$750 for reactor animals and the slaughter plant's salvage payment of \$250. The loss would be \$1,300 per animal if the owner is paid the non-reactor rate of \$450 per animal along with a \$250 salvage payment.

The potential losses without a program could be high. Extensive outbreaks would occur with losses estimated at over \$350 million to the slaughter industry. A comprehensive computer model developed in Canada in 1979 indicated that the cattle industry would eventually lose over \$1 billion annually.

Mr. DURBIN. What do you spend annually in each state on the tuberculosis program? Please break this into monitoring, indemnification, etc.

Dr. KING. I'll provide a chart which breaks out the amount spent on monitoring and surveillance, depopulation and indemnification, and disease management, by state, in FY 1993:

[The information follows:]

State	Monitoring & Surveillance	Depopulation & Indemnities 6	Disease Management	Total
Alabama	\$474		\$2,913	\$3,387
Alaska	330		2,027	2,357
Arizona	6,533		40,128	46,661
Arkansas	5,042		30,974	36,016
California	9,007		55,328	64,335
Colorado	88,448		543,324	631,772
Connecticut	403		2,477	2,880
Delaware	112		688	800
Florida	10,996		67,549	78,545
Georgia	5,825		35,780	41,605
Hawaii	323		1,985	2,308
Idaho	830		5,101	5,931
Illinois	989		6,072	7,061
Indiana	2,880		17,693	20,573
Iowa	9,637		59,200	68,837
Kansas	9,788		60,126	69,914
Kentucky	1,521		9,344	10,865
Louisiana	1,114		6,846	7,960
Maine	539		3,312	3,851
Maryland	122,744		831,441	954,185
Massachusetts	985		6,053	7,038
Michigan	2,622		16,104	18,726
Minnesota	23,654		184,022	207,676
Mississippi	1,043		6,410	7,453
Missouri	5,791		35,575	41,366
Montana	3,248		19,951	23,199
Nebraska	4,660		28,627	33,287

Nevada	1,389		8,531	9,920
New Hampshire	886		5,441	6,327
New Jersey	88		542	630
New Mexico	31,085		190,949	222,034
New York	23,753		145,908	169,661
North Carolina	8,766		53,845	62,611
North Dakota	3,756		23,070	26,826
Ohio	2,007		12,326	14,333
Oklahoma	12,933		79,449	92,382
Oregon	2,082		12,790	14,872
Pennsylvania	3,854	\$81,749	23,674	109,277
Rhode Island	204		1,254	1,458
South Carolina	5,041		30,969	36,010
South Dakota	732		4,496	5,228
Tennessee	4,954		30,430	35,384
Texas	119,980	519,904	737,019	1,376,903
Utah	345		2,117	2,462
Vermont	2,513		15,437	17,950
Virginia	2,985		18,337	21,322
Washington	1,343		8,251	9,594
West Virginia	2,000		12,286	14,286
Wisconsin	6,480		39,805	46,285
Wyoming	786		4,831	5,617
District of Columbia	14,936		104,656	119,592
Puerto Rico	46,844		287,753	334,597
TOTAL	\$619,280	\$601,653	\$3,933,216	\$5,154,149

⁶ These activities were funded from the contingency fund in FY 1993.

Mr. Durbin. Last year we had some discussions about the problem of Mexican cattle being the single biggest traceback of tuberculosis outbreaks in this country. Is that still the case and what are you doing to control the problem?

Dr. KING. Mexican cattle entering the country continue to be the single greatest source of tuberculosis lesions found at slaughter and represent a potentially dangerous threat to U.S. cattle. Of those cattle with tuberculosis lesions, the percentage of those that were of Mexican origin have increased from 66 percent in 1990 to 84 percent in FY 1993. Epidemiologic investigations involving Mexican steers have shown that approximately 67 percent of the infected imports are of the Holstein breed. This information has prompted the Mexican Government to temporarily place a ban on the exportation of all Holstein cattle to the United States.

Mexico has officially implemented a Bovine Tuberculosis Eradication program and a joint United States-Mexico Tuberculosis Committee has been formed to support initiatives aimed at disease eradication in both countries. In support of Mexico's efforts, APHIS has sponsored cooperative training programs and provided the Mexican Government with laboratory supplies and equipment for a regional tuberculosis laboratory.

In accordance with USAHA—United States Animal Health Association—resolutions, APHIS is in the process of drafting regulations which will propose official permanent identification for imported Mexican cattle, additional movement requirements for Mexican steers entering the United States, and certified documentation identifying the origin of Mexican cattle moved in interstate commerce.

TUBERCULOSIS—CERVIDAE

Mr. DURBIN. Some other Members of Congress have contacted us about problems in the commercial deer and elk herds related to tuberculosis. Do you have any authority to establish a tuberculosis indemnification, control, or monitoring program in cervidae?

Dr. KING. Currently, APHIS has the authority to regulate cattle, bison, and domestic swine exposed to infected cattle and bison, but lacks the authority to control the interstate movement of Cervidae—elk, deer, moose, and antelope. The Agency does monitor the presence of tuberculosis in these other species and is in the process of drafting a proposed rule on tuberculosis in cervids which would regulate the interstate movement of Cervidae.

APHIS developed guidelines in November 1992 to serve as the basis for a voluntary control program of tuberculosis in farmed Cervidae—deer, elk, and moose. These guidelines will be effective until the adoption of the addendum to the Bovine Tuberculosis Eradication Uniform Methods and Rules—UMR—on Tuberculosis Eradication in Cervidae. This addendum is expected to be finalized in the third quarter of FY 1994.

APHIS does not have the authority nor the funds to establish an indemnification program for Cervidae producers. However, a bill has been introduced in Congress to provide for a voluntary national insurance program to protect the owners of domesticated Cervidae against losses incurred as a result of destroying animals or herds

infected with, or exposed to, tuberculosis. The status of the bill is pending.

Mr. DURBIN. Have diagnostic tests for Cervidae been developed to allow you to proceed with a control program?

Dr. KING. Two tests have been developed for use in the diagnosis of tuberculosis in Cervidae. The BTB test, developed in New Zealand, has been evaluated for deer and elk tuberculosis detection and has proven successful. The United States collaborated with Canada in this effort using deer and elk herds undergoing depopulation in Canada following *M. bovis* confirmed herd status. APHIS has incorporated the BTB test into our proposed uniform methods and rules for its use as a supplemental test. The test will be at the expense of the owner, approximately \$100 per test, and is favored by producers in many countries.

The ELISA test, developed at Colorado State University, has been evaluated for use in Cervidae, Camelidae, and Bovidae. Over 4,000 samples were evaluated in FY 1992 through a cooperative agreement with Colorado State University. The results of these preliminary tests indicate a highly specific test with a sensitivity approaching 86 percent. Further testing will be required using a greater number of samples. Upon completion of the testing, the ELISA test will be reviewed by the United States Animal Health Association—USAHA.

WITCHWEED

Mr. DURBIN. The budget indicates that you plan to phase down the witchweed program. For the record, can you provide a table that shows the amount of witchweed infested acres in each of the past five years and what APHIS spent on the eradication program in each of those years?

Dr. KING. I'll provide a chart that displays actual and projected program status at the end of each fiscal year:

[The information follows:]

Fiscal year	Total acres infested at end of fiscal year	Acres released at end of fiscal year	Total acres released	Cost
1990	71,804	20,478	349,418	\$4,829,027
1991	56,659	14,640	369,896	5,160,027
1992	41,064	3,064	384,536	5,377,609
1993	38,000	10,000	387,600	5,588,000
1994 (est.)	25,600	12,400	397,000	4,081,000

Mr. DURBIN. Where did this pest come from and what is the significance to American agriculture?

Dr. KING. No one is sure how or when witchweed was first introduced to the United States. Witchweed was found in 1956 in North Carolina and South Carolina; it has since been discovered in 39 counties in those States. At one time, over 425,000 acres were infested.

Witchweed is an annual parasitic seed-bearing plant that attacks corn, sorghum, sugarcane, and other plants in the grass family. This pest is capable of causing severe damage to these crops. Witchweed would cost farmers an estimated \$1 billion annually, plus an estimated 10 percent loss in yield—worth \$2.4 billion—if it became widespread.

Mr. DURBIN. How quickly could you eradicate witchweed if you received the same funding level last year?

Dr. KING. APHIS would complete the witchweed program by 1997 if the program is funded at the fiscal year 1994 level. For each year that the program is funded under the FY 1994 level, the program would take an additional three years for completion.

ANIMAL WELFARE

Mr. DURBIN. Please provide a table showing by State the number of FTEs assigned to the animal welfare program. Also, if you can please provide the number of animal care facilities in each State.

Dr. KING. I'll provide a State by State accounting for the record. [The information follows:]

Full-time Equivalent Employees--FTE's--Assigned to the
Animal Welfare Program, and Number of Facilities
March 31, 1994

State	FTE's					
		Dealers	Research	Exhibitors	In transit handlers	Total
Alabama	-	15	15	18	2	50
Alaska	-	-	3	12	2	17
Arizona	1	16	10	31	12	69
Arkansas	1	134	10	21	-	165
California	14	54	190	199	25	468
Colorado	1	26	26	24	6	82
Connecticut	1	7	23	36	6	72
Delaware	1	2	7	1	-	10
District of Columbia	-	-	7	1	-	8
Florida	12	96	35	228	20	379
Georgia	2	24	19	34	23	100
Hawaii	1	5	2	15	26	48
Idaho	1	4	4	11	1	20
Illinois	3	96	55	100	5	256
Indiana	1	75	18	43	4	140
Iowa	-	379	17	17	-	413
Kansas	5	426	21	19	-	466
Kentucky	1	12	9	12	5	38
Louisiana	1	21	14	17	1	53
Maine	1	8	19	7	-	34
Maryland	21	10	42	18	6	76
Massachusetts	-	22	92	28	5	147
Michigan	1	43	41	54	1	139
Minnesota	8	109	27	37	1	174

Mississippi	-	6	7	11	-	24
Missouri	9	1073	36	32	4	1,145
Montana	-	8	5	17	-	30
Nebraska	2	189	13	11	3	216
Nevada	1	6	3	44	2	55
New Hampshire	1	3	3	16	-	22
New Jersey	1	25	62	29	5	121
New Mexico	1	5	9	10	5	29
New York	2	57	125	97	12	291
North Carolina	1	29	26	24	3	82
North Dakota	1	34	3	10	1	48
Ohio	3	69	60	46	4	179
Oklahoma	3	359	18	18	1	396
Oregon	2	82	14	29	5	130
Pennsylvania	3	157	96	76	14	343
Rhode Island	-	-	11	7	-	18
South Carolina	1	11	7	12	-	30
South Dakota	1	83	4	17	-	104
Tennessee	1	23	21	21	3	68
Texas	12	238	79	129	15	461
Utah	1	4	8	8	4	24
Vermont	1	3	5	5	-	13
Virginia	1	13	16	32	9	70
Washington	1	31	30	24	4	89
West Virginia	-	10	5	7	-	22
Wisconsin	2	38	32	67	1	138
Wyoming	-	1	2	1	-	4
Total	128	4,141	1,406	1,783	246	7,576

Mr. DURBIN. Do breeders and care facilities have to register with APHIS?

Dr. KING. Breeders of warmblooded animals who wholesale animals into the pet trade or sell them for research or exhibition purposes, must become licensed as dealers under the Animal Welfare Act. Persons who breed and sell exotic and wild animals for regulated purposes must also be licensed. Persons who breed and sell domestic animals as pets at the retail level only, do not require licensing.

Animal care facilities are registered or licensed if the animals kept there are used for research or exhibition purposes, involved in the wholesale pet trade, or are being transported in commerce. Animal care facilities such as boarding kennels, veterinary hospitals, or pet stores retailing only domestic or nondangerous animals would not be required to register or license unless they engaged in a regulated activity.

Mr. DURBIN. Describe the enforcement record of the animal welfare program for the past year.

Dr. KING. In FY 1993, APHIS animal care inspectors conducted 17,593 compliance inspections and reinspections at 9,411 facilities and sites. Carrier inspections are not included in this number because the total number of sites is in the thousands and varies greatly from year to year. Prelicensing inspections are excluded because they are not compliance inspections. With the addition of prelicensing and carrier inspections, the total number of inspections increased to 22,181. The average number of inspections per site in FY 1993 was 1.87. The number of field inspectors—veterinary medical officers and animal care inspectors—is 88 which remained consistent with FY 1992.

The average inspection rate by type of facility was Dealers 2.1; Research facilities 1.96; and Intransit handlers 1.87.

Also, during FY 1993 the program conducted 2,984 searches for unlicensed and unregistered facilities, investigated 689 complaints, and developed 921 alleged violation cases. There were 597 warnings issued, 141 stipulations paid, and 29 decisions and orders through the Administrative Law procedure. A total of \$165,250 was imposed in fines, eight licenses were suspended or revoked, and 22 cease and desist orders issued.

Mr. DURBIN. How often do your inspectors visit animal care facilities?

Dr. KING. The Animal Welfare Act requires that non-Federal research facilities receive at least the unannounced inspection per year to determine compliance. In FY 1993, APHIS personnel conducted a total of 17,593 inspections of 7,695 facilities (9,411 sites), which equates to a rate of 1.87 inspections per site.

PLANT METHODS DEVELOPMENT

Mr. DURBIN. What is the total amount spent by location on plant methods development activities in each of the past five years?

Dr. KING. I will provide a table that includes methods development laboratories locations, including satellite locations, and amounts spent at each location.

[The information follows:]

CENTER	FY 1989	FY 1990	FY 1991	FY 1992	FY 1993
Hoboken, NJ	\$560,307	\$579,895	\$511,569	\$547,739	\$568,035
Mission, TX	482,548	486,997	486,997	607,214	696,951
Gainesville, FL 1/	47,106	73,364	73,364	99,600	180,103
Guatemala City, Guatemala 1/	120,883	170,941	187,233	176,009	190,195
State College, MS 1/	92,943	119,917	119,917	104,983	111,611
Waimanalo, HI 1/	121,671	68,489	68,489	142,194	120,154
Otis Air National Guard Base, MA	945,500	970,000	1,062,500	1,100,000	1,129,500
Phoenix, AZ	493,559	2/ 718,417	2/ 711,917	2/ 774,176	2/ 805,593
Brawley, CA 1/	--	--	--	--	2/ 250,000
Whiteville, NC	365,000	365,000	400,970	425,120	438,054
Dillon, NC 1/	163,000	163,000	183,030	203,730	214,816
Gulfport, MS 1/	247,000	247,000	273,000	297,150	310,084
TOTAL	\$3,639,517	\$3,963,020	\$4,078,986	\$4,477,915	\$5,015,096

1/ Denotes satellite location.

2/ The Phoenix Center receives funds from grasshopper IPM and pink bollworm line items. The Brawley satellite location has funding from biocontrol and sweet potato whitefly line items.

Mr. DURBIN. Please provide a list of the specific pests and how much is being spent on each as part of your plant methods development program in fiscal years 1993 and 1994.

Dr. KING. I'll provide a list of the major specific pests on which the plant methods development program worked in FY 1993, and those which the program is currently working on in FY 1994.

[The information follows:]

Pests	FY 1993	FY 1994
Asian Gypsy Moth	* 189,000	* 413,380
Boll Weevil	253,020	214,437
Caribbean Fruit Fly	215,347	225,768
Gypsy Moth	904,857	** 930,429
Grasshopper	** 441,196	** 430,489
Japanese Beetle	94,537	** 154,074
Imported Fire Ant	388,598	368,849
Mediterranean Fruit Fly	* 563,080	* 755,857
Mexican Fruit Fly	713,766	623,176
Misc./Exotic Pests	135,053	134,392
Noxious Weeds	345,434	312,927
Pine Shoot Beetle	* 115,004	* 114,437
Russian Wheat Aphid	135,053	--
Pink Bollworm	** 491,427	** 600,566
Whitefly	** 298,922	** 297,459
Witchweed	402,946	365,965
TOTAL	\$5,687,240	\$5,942,205

* Includes funds from emergency programs, including Commodity Credit Corporation and Contingency fund transfers.

** Includes funds from biocontrol, grasshopper IPM, pink bollworm, or sweet potato whitefly line items.

- Final testing of a new methyl bromide fumigation enclosure was completed during FY 1993. This enclosure will ensure safer and more precise treatments in the field. In cooperation with ARS and Chile, a new non-chemical, industrial treatment for cherimoya (a tropical fruit) was developed. This treatment, which consists of soapy water and wax, has promise for use on other commodities to replace methyl bromide.
- A new method to mass rear a larval parasite of the Mexican Fruit Fly was developed during FY 1993. Improved techniques to immobilize and field-deliver the parasite were also developed.
- A new regulatory treatment for gypsy moth egg masses, as well as new pheromone dispensers for gypsy moth survey traps was developed in FY 1993. Technology for molecular identification (DNA fingerprinting) of insects was also developed.
- After field testing, four new herbicides were added this year for project use. In addition, new application techniques were developed for metham sodium (Sectagon). Sectagon fumigation has been incorporated into the witchweed project at a cost of \$335 per acre as a replacement for methyl bromide fumigation which costs \$1,500 per acre.
- Pilot studies with Gypchek (virus of the gypsy moth) were successful in eradicating small isolated infestations, with no non-target effects.
- A new chemical turf treatment has been identified for reducing Japanese beetle grub populations around airports.
- Evaluation techniques have been developed for biocontrol agents of Russian wheat aphid to determine their establishment and impact.
- Inspection, certification, and regulatory treatment systems were developed for the pine shoot beetle on Christmas trees.
- A patent was developed and submitted for an immunological identification of the khapra beetle, a potentially damaging exotic pest.
- Improved or alternative methods of fruit fly control were developed, using male annihilation, ground and aerial bait sprays, sterile insect technique, and integrated technologies.
- The program optimized the quality and quantity of diet ingredients and other aspects of the larval rearing environment with respect to yield, survival, and cost and quality of mass-reared Mediterranean fruit flies.

- The Denver Wildlife Research Center--DWRC--continues to develop and validate analytical methods of chemical analysis, and to register and reregister chemicals such as Compound 1080, strychnine alkaloid, zinc phosphide, Starlicide (DRC-1339), alpha-chloralose, and methyl anthranilate. These compounds are used for rodent, bird, and predator control, and for taste aversion. A growing proportion of the ADC methods development effort (approximately 55 percent at present), is devoted to developing alternative, nonlethal methods such as bird repellents, varietal resistance of crops to vertebrate damage, habitat manipulation, and immunocontraception.
- APHIS personnel in several western States evaluated the potential of a new breakaway snare equipped with a shear-pin lock in FY 1993. Field testing of the snare, developed at the DWRC, is continuing in order to obtain observations encompassing a variety of field conditions. The improved locks are effective in allowing deer, antelope, and cattle to release themselves.
- DWRC continues to progress in research to identify an immunocontraceptive for use on deer and other mammals as a method to resolve site-specific wildlife problems. Studies aimed at perfecting oral delivery of immunocontraceptives are continuing.
- DWRC personnel recently completed an evaluation of methyl-anthranilate as a bird repellent in aquatic situations with promising results. Birds can be repelled from water areas with new formulations that were tested. The program conducted tests, which proved successful, of an electronic device for repelling beaver from problem areas such as water control structures.
- The DWRC began a study in FY 1993 to evaluate the efficacy of three sulfur-based repellents to protect seedlings from elk and deer browsing. This study is a part of an ongoing cooperative effort with the Forest Service to identify a method for alleviating wildlife damage on reforestation units.
- DWRC scientists are studying the forward-looking infrared--FLIR--imaging technology to determine the feasibility of using airborne FLIR technology to locate and conduct censuses of coyote and other wildlife populations.
- APHIS personnel undertook studies of the brown tree snake problem in Guam under terms of an interagency agreement between the DWRC and the U.S. Fish and Wildlife Service. DWRC research has shown that methyl-bromide, as well as other fumigants and oral and dermal toxic insecticides, may be effective in controlling the pest. Fumigation of cargo that has a high risk of harboring snakes is one potential method for preventing their dispersal to other Pacific islands, including Hawaii.
- APHIS' National Veterinary Services Laboratories--NVSL--have pioneered the development of methodology for the measurement of fumonisin mycotoxins in corn and corn-based foods and feeds. Fumonisin is a toxic substance produced by a fungus that has been

associated with esophageal cancer in people and diseases which cause significant losses in swine and the death of a number of horses. Working with the Iowa State University and Pennsylvania State University, NVSL examined suspicious samples of corn and corn-based foods and found 350 contained fumonisins.

- NVSL has worked with ARS to determine the length of time the porcine reproductive and respiratory syndrome--PRRS--virus can be isolated from meat. This was in response to Russia's concern about importing meat from the United States. Pigs were inoculated with the PRRS virus and killed when the virus was at its peak. Virus was isolated from almost all the samples until the thirty second day, however, as another part of the study, we tested 600 pork carcasses randomly selected from pork being prepared for export to Russia and did not find the virus. This gives considerable assurance that the virus is not likely to be spread through international shipment of fresh U.S. pork which are processed under usual circumstances.
- NVSL has been working to develop sensitive diagnostic procedures for verifying that livestock intended for export are free of bluetongue virus--BTV--. This virus has resulted in severe import restrictions on U.S. livestock and germ plasma. The NVSL has adapted a polymerase chain reaction--PCR--procedure for the detection of BTV. The validity of the test has been evaluated by using the PCR procedure to test experimentally inoculated cattle and sheep and to test naturally infected cattle. The test has proven to be fast and reliable. Additional studies are underway to test all samples submitted to the NVSL with the PCR technique and the traditional time-consuming virus isolation procedure. We anticipate that if this comparison is successful, the PCR technique will be the method of choice to verify that U.S. livestock and germ plasma are free of BTV which should allow the export of our products to additional countries.

BIOTECHNOLOGY

Mr. DURBIN. How many permit reviews for biotechnology activities were performed during fiscal year 1993?

Dr. KING. In FY 1993, APHIS completed 139 reviews of permit applications for release and field testing of genetically engineered organisms. In addition, APHIS reviewed 292 applications for permits for movement of transgenic plants. Under the new notification process which went into effect April 30, 1993, APHIS reviewed 119 release notifications and 121 movement notifications during the last 6 months of FY 1993.

Mr. DURBIN. How many interstate movement permit reviews did APHIS perform?

Dr. KING. APHIS completed 217 reviews of permit applications for the interstate movement of genetically engineered organisms and 114 reviews of notifications for interstate movement. These figures do not include permit reviews for the importation of such organisms, nor for the issuance of courtesy permits for movement of genetically engineered organisms that are similar to, but not regulated organisms.

Mr. DURBIN. What is the average length of time that each of these reviews took?

Dr. KING. The average length of time for these reviews will be provided.

[The information follows:]

Permit:

Release—82 days.

Importation—28 days.

Interstate—41 days.

Notification:

Release—20 days.

Importation—13 days.

Interstate—9 days.

Release/interstate—25 days.

Mr. DURBIN. Please provide a five-year staffing and funding table, beginning with fiscal year 1990, showing the resources for biotechnology efforts.

Dr. KING. See the following table.

[The information follows:]

ANIMAL AND PLANT HEALTH INSPECTION SERVICE STAFFING AND FUNDING FOR
BIOTECHNOLOGY—FISCAL YEARS 1990–94

[In thousands of dollars]

	1990	1991	1992	1993	1994
Funding	\$3,157	\$3,952	\$4,500	\$4,571	\$4,634
Staff years	50	55	60	59	58

Note.—The environmental component of the biotechnology line-item has not been included in this table.

Mr. DURBIN. For the record, please provide a list of pending or approved genetically modified organisms that would be introduced into the environment that were subject to review and/or approval by APHIS.

Dr. KING. I would be pleased to do so. Please note that the pending genetically modified organisms are not included. This information is not available to the public until after publication in the Federal Register.

[The information follows:]

BIOTECHNOLOGY RELEASE PERMITS ISSUED

Date rec'd	Date issued	Institution	Sites	Bp number	Reg article cat	Intro type
16-Jun-87	23-Dec-87	Calgene	1	87-167-01r	Tomato	Release
27-Jul-87	21-Dec-87	Calgene	1	87-208-01r	Tomato	Release
14-Aug-87	28-Dec-87	Du Pont	1	87-226-01r	Tomato	Release
17-Aug-87	25-Nov-87	Calgene	1	87-229-01r	Tobacco	Release
17-Aug-87	11-Dec-87	Calgene	1	87-229-02r	Tobacco	Release
25-Nov-87	23-Mar-88	Monsanto	1	87-329-01r	Tomato	Release
25-Nov-87	23-Mar-88	Monsanto	1	87-329-02r	Tomato	Release
27-Nov-87	22-Mar-88	Du Pont	1	87-331-01r	Tomato	Release
21-Dec-87	25-May-88	Crop Genetics	1	87-355-01r	Clavibacter	Release
11-Jan-88	25-Apr-88	Monsanto	1	88-011-01r	Tomato	Release
27-Jan-88	06-Jun-88	Iowa State U	1	88-027-03r	Tobacco	Release
28-Jan-88	24-May-88	Agrigenetics	1	88-028-01r	Tobacco	Release
29-Jan-88	23-May-88	Agrigenetics	1	88-029-02r	Tomato	Release
05-Feb-88	27-Apr-88	Sandoz	1	88-036-01r	Tobacco	Release
10-Feb-88	05-May-88	Monsanto	1	88-041-01r	Tomato	Release
10-Feb-88	23-May-88	Monsanto	1	88-041-04r	Tomato	Release
10-Feb-88	23-May-88	Monsanto	1	88-041-07r	Tomato	Release
23-Feb-88	28-Apr-88	Sandoz	1	88-054-01r	Tobacco	Release
31-Mar-88	28-Jul-88	Du Pont	1	88-091-01r	Tobacco	Release
01-Apr-88	22-Jun-88	Du Pont	1	88-092-01r	Tomato	Release
23-Aug-88	14-Dec-88	Calgene	1	88-236-01r	Tomato	Release
09-Nov-88	22-Feb-89	Monsanto	1	88-314-05r	Tomato	Release
28-Nov-88	13-Mar-89	Rohm and Haas	1	88-333-02r	Tobacco	Release
09-Dec-88	06-Apr-89	Calgene	1	88-344-07r	Tomato	Release
16-Dec-88	30-Mar-89	Calgene	1	88-351-12r	Tomato	Release
16-Dec-88	13-Apr-89	Agracetus	1	88-351-13r	Cotton	Release
20-Dec-88	27-Apr-89	Crop Genetics	4	88-355-01r	Clavibacter	Release
30-Jan-89	28-Apr-89	Monsanto	1	89-030-02r	Tomato	Release
30-Jan-89	03-May-89	Monsanto	1	89-030-03r	Potato	Release
30-Jan-89	26-Apr-89	Monsanto	1	89-030-04r	Potato	Release
03-Feb-89	03-May-89	Monsanto	1	89-034-10r	Cotton	Release
03-Feb-89	04-May-89	Monsanto	1	89-034-11r	Soybean	Release
03-Feb-89	08-May-89	Monsanto	1	89-034-12r	Soybean	Release
03-Feb-89	08-May-89	Monsanto	1	89-034-15r	Soybean	Release
07-Feb-89	30-Jun-89	Northrup King	1	89-038-01r	Alfalfa	Release
07-Feb-89	06-Jun-89	Northrup King	1	89-038-03r	Alfalfa	Release
16-Feb-89	26-Apr-89	Monsanto	1	89-047-04r	Tomato	Release
16-Feb-89	24-May-89	Calgene	1	89-047-07r	Cotton	Release
22-Feb-89	22-Jun-89	Crop Genetics	1	89-053-01r	Clavibacter	Release
06-Mar-89	19-May-89	U of Kentucky	1	89-065-01r	Tobacco	Release
14-Mar-89	30-Jun-89	Monsanto	1	89-073-01r	Tomato	Release
15-Mar-89	13-Jul-89	Calgene	1	89-074-01r	Tobacco	Release
07-Apr-89	30-Jun-89	Iowa State U	1	89-097-01r	Tobacco	Release
19-Apr-89	28-Jul-89	Iowa State U	1	89-109-03r	Poplar	Release
26-Apr-89	06-Jul-89	BioTechnica	1	89-116-20r	Tobacco	Release
16-May-89	11-Aug-89	Pioneer	1	89-136-01r	Alfalfa	Release
16-May-89	14-Aug-89	Calgene	1	89-136-04r	Tobacco	Release
30-May-89	11-Oct-89	Monsanto	1	89-150-01r	Cotton	Release
21-Jun-89	14-Aug-89	New York State Exp Stn	1	89-172-01r	Cucumber	Release
11-Jul-89	10-Oct-89	Calgene	1	89-192-01r	Cotton	Release
27-Jul-89	21-Nov-89	Monsanto	1	89-208-01r	Soybean	Release
08-Aug-89	15-Feb-90	U of California/Davis	1	89-220-01r	Walnut	Release
14-Sep-89	21-Feb-90	ARS	1	89-257-04r	Potato	Release
05-Oct-89	23-Jan-90	Monsanto	1	89-278-01r	Tomato	Release
05-Oct-89	02-Feb-90	Monsanto	1	89-278-02r	Tomato	Release
17-Oct-89	16-Feb-90	Auburn U	1	89-290-01r	Xanthomonas	Release

BIOTECHNOLOGY RELEASE PERMITS ISSUED

Date rec'd	Date issued	Institution	Sites	Bp number	Reg article cat	Intro type
20-Oct-89	14-Feb-90	Monsanto	1	89-293-01r	Tomato	Release
27-Oct-89	21-Feb-90	Upjohn	1	89-300-01r	Melon, Squash	Release
01-Nov-89	01-Mar-90	Upjohn	1	89-305-01r	Melon, Squash	Release
01-Nov-89	01-Mar-90	Upjohn	1	89-305-03r	Melon, Squash	Release
07-Nov-89	01-Mar-90	Upjohn	1	89-311-01r	Melon, Squash	Release
16-Nov-89	12-Feb-90	Calgene	1	89-320-01r	Tomato	Release
22-Nov-89	21-Mar-90	Ciba-Geigy	1	89-326-03r	Tobacco	Release
05-Dec-89	05-Apr-90	Northrup King	1	89-339-01r	Cotton	Release
28-Dec-89	19-Apr-90	Rohm and Haas	1	89-362-01r	Tobacco	Release
16-Jan-90	09-May-90	Crop Genetics	1	90-016-01r	Clavibacter	Release
16-Jan-90	11-Apr-90	Calgene	2	90-016-04r	Cotton	Release
19-Jan-90	19-Mar-90	Calgene	1	90-019-01r	Tomato	Release
23-Jan-90	15-May-90	Monsanto	1	90-023-01r	Cotton	Release
25-Jan-90	16-Apr-90	Monsanto	2	90-025-01r	Cotton	Release
25-Jan-90	10-May-90	Monsanto	2	90-025-05r	Cotton	Release
29-Jan-90	31-May-90	Louisiana State U	1	90-029-01r	Rice	Release
31-Jan-90	23-May-90	ARS	1	90-031-02r	Potato	Release
01-Feb-90	08-May-90	Monsanto	1	90-032-01r	Potato	Release
01-Feb-90	27-Apr-90	Monsanto	6	90-032-02r	Cotton	Release
01-Feb-90	19-Apr-90	Monsanto	1	90-032-03r	Potato	Release
02-Feb-90	31-May-90	BioTechnica	1	90-033-01r	Corn	Release
07-Feb-90	07-May-90	Monsanto	1	90-038-02r	Tomato	Release
07-Feb-90	15-May-90	Monsanto	1	90-038-03r	Soybean	Release
07-Feb-90	23-May-90	Monsanto	11	90-038-04r	Soybean	Release
07-Feb-90	09-May-90	Monsanto	3	90-038-05r	Soybean	Release
12-Feb-90	19-Apr-90	Upjohn	1	90-043-02r	Tomato	Release
13-Feb-90	11-May-90	Du Pont	1	90-044-05r	Cotton	Release
28-Feb-90	31-May-90	New York State Exp Str	1	90-059-01r	Cucumber	Release
06-Mar-90	06-Jul-90	Canners Seed	1	90-065-01r	Tomato	Release
06-Mar-90	15-May-90	U of Kentucky	1	90-065-06r	Tobacco	Release
07-Mar-90	09-May-90	Calgene	1	90-066-01r	Tomato	Release
12-Mar-90	21-Jun-90	U of Kentucky	1	90-071-02r	Tobacco	Release
29-Mar-90	11-Jul-90	Upjohn	3	90-088-01r	Melon, Squash	Release
29-Mar-90	06-Jul-90	Upjohn	1	90-088-02r	Melon, Squash	Release
29-Mar-90	03-Jul-90	Upjohn	3	90-088-03r	Melon, Squash	Release
18-Apr-90	12-Sep-90	Calgene	1	90-108-03r	Cotton	Release
24-Apr-90	05-Jun-90	Pioneer	1	90-114-01r	Alfalfa	Release
01-May-90	05-Jul-90	Pennsylvania State U	1	90-121-01r	Rice	Release
15-May-90	04-Sep-90	U of Wisconsin	1	90-135-01r	Pseudomonas	Release
15-May-90	15-Aug-90	Amoco	1	90-135-02r	Tobacco	Release
13-Jun-90	17-Jul-90	U of Wisconsin	1	90-164-03r	N/A	Courtesy
26-Jun-90	20-Sep-90	Monsanto	1	90-177-01r	Cotton	Release
03-Jul-90	14-Sep-90	Monsanto	1	90-184-01r	Soybean	Release
06-Sep-90	16-Oct-90	Calgene	1	90-249-01r	Tomato	Release
01-Oct-90	15-Nov-90	Upjohn	1	90-274-05r	Soybean	Release
09-Oct-90	07-Jan-91	Monsanto	1	90-282-01r	Potato	Release
24-Oct-90	06-Mar-91	Calgene	1	90-297-01r	Cotton	Release
30-Oct-90	06-Mar-91	Calgene	12	90-303-02r	Cotton	Release
06-Nov-90	20-Mar-91	ARS	4	90-310-01r	Potato	Release
06-Nov-90	28-Dec-90	Calgene	1	90-310-02r	Tomato	Release
07-Nov-90	12-Mar-91	Frito Lay	1	90-311-01r	Potato	Release
28-Nov-90	17-Apr-91	ARS	4	90-332-01r	Potato	Release
28-Nov-90	12-Mar-91	DeKalb	1	90-332-02r	Corn	Release
28-Nov-90	06-Mar-91	DeKalb	1	90-332-04r	Corn	Release
29-Nov-90	02-Apr-91	Crop Genetics	2	90-333-01r	Clavibacter	Release
10-Dec-90	02-Apr-91	DNA Plant Tech	1	90-344-01r	Tobacco	Release
11-Dec-90	02-May-91	ARS	4	90-345-01r	Potato	Release
11-Dec-90	02-May-91	Washington State U	1	90-345-02r	Potato	Release
13-Dec-90	12-Apr-91	Monsanto	5	90-347-01r	Cotton	Release
13-Dec-90	09-Apr-91	North Carolina State U	1	90-347-04r	Tobacco	Release

BIOTECHNOLOGY RELEASE PERMITS ISSUED

Date rec'd	Date issued	Institution	Sites	Bp number	Reg article cat	Intro type
17-Dec-90	15-Mar-91	ARS	1	90-351-01r	Walnut	Release
17-Dec-90	18-Apr-91	Calgene	1	90-351-02r	Potato	Release
19-Dec-90	18-Apr-91	Ciba-Geigy	1	90-353-01r	Tobacco	Release
26-Dec-90	24-Apr-91	ARS	1	90-360-01r	Potato	Release
31-Dec-90	19-Mar-91	U of California/Davis	1	90-365-01r	Tomato	Release
31-Dec-90	02-Apr-91	Upjohn	3	90-365-02r	Melon, Squash	Release
31-Dec-90	02-Apr-91	Upjohn	1	90-365-03r	Melon, Squash	Release
07-Jan-91	02-May-91	Monsanto	1	91-007-01r	Cotton	Release
07-Jan-91	26-Apr-91	Monsanto	3	91-007-04r	Potato	Release
07-Jan-91	03-May-91	AlS	4	91-007-06r	Potato	Release
07-Jan-91	01-May-91	BioSource	1	91-007-08r	TMV	Release
11-Jan-91	30-May-91	Monsanto	1	91-011-01r	Tomato	Release
11-Jan-91	14-May-91	Monsanto	3	91-011-04r	Potato	Release
14-Jan-91	04-Jun-91	Rogers NK	1	91-014-01r	Tomato	Release
14-Jan-91	04-Jun-91	Rogers NK	1	91-014-02r	Tomato	Release
16-Jan-91	01-May-91	Du Pont	2	91-016-01r	Tobacco	Release
18-Jan-91	24-Apr-91	Monsanto	4	91-018-01r	Soybean	Release
18-Jan-91	02-Apr-91	Monsanto	2	91-018-04r	Cotton	Release
23-Jan-91	19-Apr-91	Auburn U	1	91-023-06r	Pseudomonas	Courtesy
24-Jan-91	14-May-91	Monsanto	3	91-024-01r	Potato	Release
24-Jan-91	31-May-91	ARS	1	91-024-04r	Potato	Release
25-Jan-91	01-May-91	BioTechnica	4	91-025-01r	Corn	Release
25-Jan-91	01-May-91	Du Pont	3	91-025-02r	Cotton	Release
25-Jan-91	10-May-91	Ciba-Geigy	1	91-025-03r	Corn	Release
25-Jan-91	21-May-91	Rohm and Haas	1	91-025-05r	Tobacco	Release
30-Jan-91	10-May-91	Monsanto	1	91-030-01r	Corn	Release
30-Jan-91	17-May-91	Monsanto	1	91-030-04r	Potato	Release
04-Feb-91	10-May-91	Campbell	1	91-035-06r	Tomato	Release
04-Feb-91	19-Apr-91	Calgene	2	91-035-07r	Cotton	Release
08-Feb-91	22-May-91	ARS	1	91-039-01r	Potato	Release
11-Feb-91	31-May-91	AgriGenetics	1	91-042-01r	Rapeseed	Release
11-Feb-91	26-Apr-91	Auburn U	1	91-042-02r	Xanthomonas	Release
12-Feb-91	10-May-91	Louisiana State U	1	91-043-01r	Rice	Release
13-Feb-91	02-May-91	Campbell	1	91-044-01r	Tomato	Release
19-Feb-91	22-May-91	Calgene	1	91-050-01r	Tomato	Release
19-Feb-91	05-Jun-91	Monsanto	1	91-050-02r	Potato	Release
20-Feb-91	22-May-91	Monsanto	8	91-051-01r	Soybean	Release
20-Feb-91	30-May-91	Upjohn	3	91-051-03r	Soybean	Release
21-Feb-91	18-Jun-91	Montana State U	1	91-052-02r	Potato	Release
21-Feb-91	15-May-91	Pioneer	1	91-052-06r	Corn	Release
21-Feb-91	26-Apr-91	Pioneer	1	91-052-07r	Alfalfa	Release
21-Feb-91	24-Apr-91	Pioneer	1	91-052-08r	Alfalfa	Release
22-Feb-91	07-Jun-91	Upjohn	1	91-053-01r	Tomato	Release
08-Mar-91	10-Jun-91	Pioneer	1	91-067-01r	Sunflower	Release
13-Mar-91	13-May-91	Garst	1	91-072-01r	Corn	Release
15-Mar-91	05-Jun-91	Upjohn	2	91-074-01r	Corn	Release
15-Mar-91	07-Jun-91	New York State Exp Stn	1	91-074-03r	Cucumber	Release
18-Mar-91	18-Jun-91	Harris Moran	1	91-077-01r	Melon	Release
19-Mar-91	05-Jun-91	DNA Plant Tech	1	91-078-01r	Tomato	Release
20-Mar-91	18-Jun-91	DNA Plant Tech	1	91-079-01r	Tomato	Release
21-Mar-91	07-Jun-91	U of Wisconsin	1	91-080-01r	Alfalfa	Release
04-Apr-91	25-Jun-91	Monsanto	1	91-094-01r	Potato	Release
10-Apr-91	28-Jun-91	Ciba-Geigy	1	91-100-01r	Corn	Release
12-Apr-91	03-Jun-91	U of Kentucky	1	91-102-01r	Tobacco	Release
15-Apr-91	27-Jun-91	Pioneer	1	91-105-01r	Corn	Release
16-Apr-91	13-Aug-91	DNA Plant Tech	3	91-106-01r	Chrysanthemum	Release
17-Apr-91	11-Jul-91	Calgene	1	91-107-04r	Tomato	Release
17-Apr-91	18-Jun-91	Calgene	2	91-107-06r	Cotton	Release
25-Apr-91	20-Jun-91	ARS	1	91-115-01r	Tobacco	Release
03-May-91	08-Jul-91	Amoco	1	91-123-01r	Tobacco	Release

BIOTECHNOLOGY RELEASE PERMITS ISSUED

Date rec'd	Date issued	Institution	Sites	Bp number	Reg article cat	Intro type
09-May-91	01-Jul-91	Holdens	1	91-129-01r	Corn	Release
24-May-91	16-Sep-91	Monsanto	1	91-144-01r	Cotton	Release
31-May-91	24-Sep-91	Monsanto	1	91-151-01r	Soybean	Release
05-Jun-91	29-Aug-91	U of Florida	1	91-156-01r	Tobacco	Release
17-Jun-91	15-Oct-91	Calgene	3	91-168-01r	Rapeseed	Release
16-Jul-91	24-Sep-91	Pioneer	1	91-197-01r	Corn	Release
16-Jul-91	24-Sep-91	Pioneer	1	91-197-02r	Corn	Release
22-Jul-91	04-Oct-91	Upjohn	1	91-203-01r	Soybean	Release
24-Jul-91	22-Oct-91	Calgene	2	91-205-01r	Rapeseed	Release
24-Jul-91	19-Nov-91	PetoSeed	1	91-205-02r	Tomato	Release
06-Aug-91	04-Oct-91	Upjohn	1	91-218-02r	Corn	Release
06-Aug-91	04-Nov-91	U of California/Davis	1	91-218-03r	Apple	Release
10-Sep-91	15-Jan-92	U of Hawaii/Manoa	1	91-253-01r	Papaya	Release
25-Sep-91	17-Dec-91	Calgene	1	91-268-01r	Tomato	Release
25-Sep-91	30-Dec-91	Ciba-Geigy	1	91-268-02r	Tobacco	Release
21-Oct-91	04-Dec-91	Frito-Lay	1	91-294-02r	Potato	Release
22-Oct-91	04-Feb-92	Holdens	1	91-295-01r	Corn	Release
28-Oct-91	03-Feb-92	Frito-Lay	1	91-301-01r	Potato	Release
29-Oct-91	14-Feb-92	Frito-Lay	1	91-302-01r	Potato	Release
29-Oct-91	23-Dec-91	Cargill	1	91-302-02r	Corn	Release
30-Oct-91	03-Mar-92	Frito-Lay	1	91-303-01r	Potato	Release
13-Nov-91	22-Jan-92	DeKalb	1	91-317-01r	Corn	Release
18-Nov-91	04-Feb-92	North Carolina State U	2	91-322-01r	Tobacco	Release
20-Nov-91	28-Feb-92	Frito-Lay	1	91-324-01r	Potato	Release
20-Nov-91	19-Mar-92	Frito-Lay	1	91-324-03r	Potato	Release
22-Nov-91	07-Feb-92	Monsanto	1	91-326-01r	Tomato	Release
22-Nov-91	19-Mar-92	Frito-Lay	1	91-326-02r	Potato	Release
22-Nov-91	13-Mar-92	Monsanto	1	91-326-03r	Tomato	Release
25-Nov-91	06-Mar-92	Calgene	1	91-329-01r	Cotton	Release
25-Nov-91	06-Mar-92	Calgene	5	91-329-02r	Cotton	Release
25-Nov-91	20-Mar-92	Calgene	6	91-329-03r	Cotton	Release
25-Nov-91	06-Mar-92	Calgene	1	91-329-04r	Cotton	Release
29-Nov-91	14-Jan-92	Calgene	1	91-333-02r	Cotton	Release
29-Nov-91	20-Apr-92	Calgene	1	91-333-03r	Cotton	Release
09-Dec-91	06-Apr-92	Crop Genetics	2	91-343-01r	Clavibacter	Release
09-Dec-91	06-Apr-92	Pioneer	5	91-343-02r	Alfalfa	Release
12-Dec-91	16-Apr-92	Calgene	3	91-346-01r	Rapeseed	Release
12-Dec-91	07-Feb-92	Pioneer	1	91-346-02r	Soybean	Release
13-Dec-91	14-Apr-92	Monsanto	1	91-347-01r	Cotton	Release
13-Dec-91	15-Apr-92	Monsanto	19	91-347-02r	Cotton	Release
13-Dec-91	14-Apr-92	Monsanto	2	91-347-03r	Cotton	Release
16-Dec-91	20-Apr-92	U of Idaho	1	91-350-01r	Potato	Release
18-Dec-91	13-Apr-92	Calgene	2	91-352-01r	Rapeseed	Release
18-Dec-91	15-Apr-92	Pioneer	1	91-352-02r	Alfalfa	Release
18-Dec-91	17-Mar-92	Frito-Lay	1	91-352-03r	Potato	Release
18-Dec-91	27-Apr-92	Frito-Lay	1	91-352-04r	Potato	Release
19-Dec-91	17-Apr-92	DNA Plant Tech	1	91-353-01r	Tobacco	Release
19-Dec-91	06-Mar-92	U of California/Davis	1	91-353-02r	Tomato	Release
23-Dec-91	17-Apr-92	Calgene	4	91-357-01r	Cotton	Release
23-Dec-91	15-Apr-92	Calgene	2	91-357-02r	Potato	Release
24-Dec-91	21-Apr-92	Du Pont	6	91-358-01r	Cotton	Release
24-Dec-91	06-Mar-92	Applied Starch Tech	1	91-358-02r	Potato	Release
27-Dec-91	20-Apr-92	Monsanto	7	91-360-01r	Potato	Release
30-Dec-91	05-May-92	Dow	1	91-364-01r	Amelanchier laevis	Release
01-Jan-92	29-Apr-92	Monsanto	2	92-002-01r	Potato	Release
01-Jan-92	29-Apr-92	Monsanto	2	92-002-02r	Potato	Release
01-Jan-92	16-Apr-92	Pioneer	1	92-002-03r	Corn	Release
01-Jan-92	30-Apr-92	Pioneer	3	92-002-04r	Corn	Release
01-Jan-92	05-May-92	Pioneer	1	92-002-05r	Corn	Release
07-Jan-92	29-Apr-92	Monsanto	1	92-007-01r	Soybean	Release

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Date rec'd	Date issued	Institution	Sites	Bp number	Reg article cat	Intr type
07-Jan-92	06-May-92	Monsanto	5	92-007-02r	Soybean	Release
07-Jan-92	06-May-92	Monsanto	2	92-007-03r	Soybean	Release
10-Jan-92	31-Mar-92	Louisiana State U	1	92-010-01r	Rice	Release
14-Jan-92	29-Apr-92	North Carolina State U	1	92-014-01r	Tobacco	Release
15-Jan-92	11-May-92	Monsanto	1	92-015-01r	Soybean	Release
15-Jan-92	30-Apr-92	Monsanto	2	92-015-02r	Soybean	Release
15-Jan-92	24-Apr-92	Monsanto	1	92-015-03r	Soybean	Release
15-Jan-92	14-May-92	Monsanto	2	92-015-04r	Soybean	Release
15-Jan-92	05-May-92	Monsanto	1	92-015-05r	Soybean	Release
16-Jan-92	14-May-92	AHS	1	92-016-01r	Potato	Release
17-Jan-92	11-May-92	InterMountain Canola	1	92-017-01r	Rapeseed	Release
17-Jan-92	14-May-92	Northrup King	2	92-017-02r	Corn	Release
17-Jan-92	14-May-92	Northrup King	4	92-017-03r	Corn	Release
17-Jan-92	15-May-92	Hoechst-Roussel	5	92-017-04r	Corn	Release
21-Jan-92	22-May-92	ARS	1	92-021-01r	Potato	Release
22-Jan-92	21-May-92	Pioneer	4	92-022-01r	Soybean	Release
22-Jan-92	01-Apr-92	Pioneer	1	92-022-02r	Corn	Release
22-Jan-92	04-May-92	Pioneer	1	92-022-03r	Corn	Release
22-Jan-92	21-May-92	Calgene	3	92-022-04r	Tomato	Release
22-Jan-92	09-Apr-92	Upjohn	4	92-027-01r	Melon, Squash	Release
27-Jan-92	09-Apr-92	Upjohn	1	92-027-02r	Melon, Squash	Release
27-Jan-92	09-Apr-92	Upjohn	1	92-028-01r	Tomato	Release
28-Jan-92	27-May-92	Purdue U	1	92-034-01r	Corn	Release
03-Feb-92	27-Apr-92	DeKalb	4	92-034-02r	Potato	Release
03-Feb-92	12-May-92	ARS	1	92-034-03r	Tomato	Release
03-Feb-92	14-May-92	Heinz	1	92-035-01r	Tomato	Release
04-Feb-92	07-May-92	Rogers NK	1	92-035-03r	Tomato	Release
04-Feb-92	24-Apr-92	Campbell	1	92-035-05r	Tomato	Release
04-Feb-92	04-May-92	DNA Plant Tech	1	92-036-01r	Potato	Release
05-Feb-92	26-May-92	Washington State U	1	92-037-01r	Tomato	Release
06-Feb-92	14-May-92	Monsanto	2	92-037-02r	Soybean	Release
06-Feb-92	03-Jun-92	Monsanto	1	92-037-03r	Soybean	Release
06-Feb-92	19-May-92	Monsanto	1	92-037-04r	Corn	Release
06-Feb-92	19-May-92	Monsanto	40	92-037-05r	Soybean	Release
06-Feb-92	01-May-92	Monsanto	21	92-037-06r	Soybean	Release
06-Feb-92	21-May-92	Monsanto	13	92-037-07r	Melon, Squash	Release
06-Feb-92	18-May-92	Upjohn	18	92-041-01r	Soybean	Release
10-Feb-92	05-May-92	Monsanto	2	92-041-02r	Alfalfa	Release
10-Feb-92	21-May-92	Northrup King	1	92-042-01r	Corn	Release
11-Feb-92	27-May-92	Ciba-Geigy	1	92-042-02r	Sunflower	Release
11-Feb-92	29-Apr-92	Pioneer	2	92-043-01r	Corn	Release
12-Feb-92	05-Jun-92	Hoechst-Roussel	4	92-043-02r	Soybean	Release
12-Feb-92	22-May-92	Upjohn	3	92-043-03r	Soybean	Release
12-Feb-92	21-May-92	Upjohn	5	92-045-01r	Potato	Release
14-Feb-92	12-May-92	ARS	5	92-045-02r	Potato	Release
14-Feb-92	12-May-92	ARS	2	92-049-01r	Tomato	Release
18-Feb-92	21-May-92	Monsanto	1	92-049-02r	Rapeseed	Release
18-Feb-92	05-Jun-92	InterMountain Canola	1	92-049-03r	Tomato	Release
18-Feb-92	15-Apr-92	PetoSeed	1	92-049-04r	Corn	Release
18-Feb-92	14-May-92	DeKalb	2	92-049-05r	Corn	Release
18-Feb-92	29-Apr-92	Upjohn	1	92-052-01r	Tobacco	Release
21-Feb-92	20-May-92	U of Arizona	1	92-055-01r	Soybean	Release
24-Feb-92	20-May-92	Monsanto	1	92-056-01r	Corn	Release
25-Feb-92	29-May-92	ICI	1	92-062-01r	Tomato	Release
02-Mar-92	05-Jun-92	Campbell	5	92-065-01r	Potato	Release
05-Mar-92	15-May-92	ARS	2	92-066-01r	Corn	Release
06-Mar-92	04-Jun-92	Holdens	1	92-073-01r	Tobacco	Release
13-Mar-92	30-Jun-92	American Cyanamid	1	92-073-02r	Soybean	Release
13-Mar-92	14-May-92	Monsanto	3	92-073-03r	Soybean	Release
13-Mar-92	14-May-92	Monsanto	1	92-076-01r	Tomato	Release
16-Mar-92	01-Jun-92	Monsanto				

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Date rec'd	Date issued	Institution	Sites	Bp number	Reg article cat	Intro type
16-Mar-92	18-Jun-92	New York State Exp Stn	1	92-076-02r	Melon, Squash, Tomato	Release
17-Mar-92	01-Jun-92	Pioneer	1	92-077-01r	Corn	Release
20-Mar-92	04-May-92	U of Idaho	1	92-080-01r	Potato	Release
20-Mar-92	04-May-92	Harris Moran	1	92-080-02r	Melon	Release
20-Mar-92	22-May-92	Montana State U	3	92-080-03r	Potato	Release
20-Mar-92	03-Jun-92	Upjohn	2	92-080-04r	Corn	Release
20-Mar-92	22-May-92	Cargill	1	92-080-05r	Corn	Release
24-Mar-92	05-Jun-92	ARS	1	92-084-01r	Potato	Release
25-Mar-92	12-Jun-92	AgriTope	1	92-085-01r	Tomato	Release
30-Mar-92	01-Jun-92	Upjohn	1	92-090-01r	Soybean	Release
30-Mar-92	29-May-92	Monsanto	1	92-090-02r	Potato	Release
30-Mar-92	10-Jun-92	Monsanto	1	92-090-03r	Tomato	Release
06-Apr-92	05-Jun-92	Stine Seeds	1	92-097-01r	Soybean	Release
14-Apr-92	09-Jun-92	Calgene	2	92-105-01r	Cotton	Release
14-Apr-92	18-Jun-92	Holdens	1	92-105-02r	Corn	Release
15-Apr-92	25-Jun-92	Calgene	3	92-106-01r	Cotton	Release
17-Apr-92	09-Jun-92	Monsanto	1	92-108-01r	Soybean	Release
22-Apr-92	09-Jun-92	U of Wisconsin/Madison	1	92-113-01r	Pseudomonas	Release
06-May-92	01-Sep-92	Ciba-Geigy	1	92-127-01r	Corn	Release
12-May-92	11-Jun-92	Amoco	1	92-133-01r	Tobacco	Release
19-May-92	11-Sep-92	Ciba-Geigy	1	92-140-01r	Corn	Release
04-Jun-92	23-Sep-92	Calgene	1	92-156-01r	Rapeseed	Release
11-Jun-92	08-Jul-92	Calgene	2	92-163-01r	Rapeseed	Release
12-Jun-92	10-Aug-92	DeKalb	1	92-164-01r	Corn	Release
12-Jun-92	30-Jul-92	MSU	1	92-164-02r	Melon	Release
17-Jun-92	29-Sep-92	DeKalb	1	92-169-01r	Corn	Release
17-Jun-92	13-Oct-92	Northrup King	2	92-169-02r	Corn	Release
22-Jun-92	21-Jul-92	Pioneer	1	92-174-01r	Soybean	Release
22-Jun-92	03-Nov-92	Pioneer	1	92-174-02r	Corn	Release
23-Jun-92	28-Aug-92	Upjohn	1	92-175-01r	Corn	Release
24-Jun-92	28-Sep-92	Monsanto	4	92-176-01r	Tomato	Release
30-Jun-92	02-Oct-92	Upjohn	2	92-182-01r	Soybean	Release
01-Jul-92	10-Oct-92	Noble Foundation	1	92-183-01r	Alfalfa	Release
09-Jul-92	09-Nov-92	ARS	1	92-191-01r	Plum	Release
21-Jul-92	16-Oct-92	Pioneer	1	92-203-01r	Soybean	Release
27-Jul-92	21-Oct-92	Pioneer	1	92-209-01r	Corn	Release
27-Jul-92	02-Nov-92	Monsanto	1	92-209-02r	Corn	Release
27-Jul-92	17-Nov-92	Monsanto	1	92-209-03r	Corn	Release
30-Jul-92	16-Nov-92	Pioneer	1	92-212-01r	Corn	Release
05-Aug-92	31-Aug-92	Auburn U	1	92-218-01r	Xanthomonas	Release
06-Aug-92	31-Aug-92	Calgene	2	92-219-01r	Tomato	Release
17-Aug-92	10-Nov-92	Pioneer	1	92-230-01r	Soybean	Release
19-Aug-92	17-Dec-92	Monsanto	1	92-232-01r	Corn	Release
31-Aug-92	19-Apr-93	Calgene	56	92-244-01r	Rapeseed	Release
31-Aug-92	08-Oct-92	Holdens	2	92-244-02r	Corn	Release
31-Aug-92	21-Oct-92	Holdens	1	92-244-03r	Corn	Release
01-Sep-92	21-Oct-92	AgriPro	1	92-245-01r	Soybean	Release
01-Sep-92	21-Oct-92	Cargill	1	92-245-02r	Corn	Release
11-Sep-92	23-Nov-92	ICI	1	92-255-01r	Corn	Release
15-Sep-92	04-Dec-92	Northrup King	1	92-259-01r	Soybean	Release
16-Sep-92	08-Jan-93	Rogers NK	1	92-260-01r	Petunia	Release
16-Sep-92	19-Nov-92	Monsanto	1	92-260-02r	Soybean	Release
17-Sep-92	20-Nov-92	Monsanto	2	92-261-01r	Soybean	Release
18-Sep-92	02-Nov-92	Monsanto	1	92-262-01r	Corn	Release
18-Sep-92	23-Nov-92	Monsanto	2	92-262-02r	Potato	Release
21-Sep-92	02-Nov-92	Monsanto	1	92-265-01r	Corn	Release
21-Sep-92	04-Dec-92	Monsanto	1	92-265-02r	Corn	Release
05-Oct-92	03-Feb-93	Monsanto	1	92-279-01r	Tomato	Release
27-Oct-92	12-Feb-93	DNA Plant Tech	2	92-301-01r	Tomato	Release
11-Nov-92	07-Dec-92	Upjohn	1	92-308-01r	Soybean	Release

BIOTECHNOLOGY RELEASE PERMITS ISSUED

Date rec'd	Date issued	Institution	Sites	Bp number	Reg article cat	Intro type
13-Nov-92	30-Apr-93	Pioneer	1	92-318-02r	Corn	Release
17-Nov-92	09-Feb-93	Pioneer	1	92-322-01r	Alfalfa	Release
20-Nov-92	14-Apr-93	Washington State U	2	92-325-01r	Potato	Release
24-Nov-92	08-Apr-93	Crop Genetics	10	92-329-01r	Corn	Release
25-Nov-92	13-Apr-93	Pioneer	2	92-330-01r	Corn	Release
25-Nov-92	02-Mar-93	North Carolina State U	1	92-330-02r	Tobacco	Release
30-Nov-92	22-Apr-93	Monsanto	19	92-335-01r	Soybean	Release
08-Dec-92	12-Feb-93	Calgene	8	92-343-01r	Tomato	Release
14-Dec-92	02-Mar-93	Frito-Lay	1	92-349-01r	Potato	Release
14-Dec-92	11-Feb-93	Frito-Lay	1	92-349-02r	Potato	Release
14-Dec-92	02-Mar-93	Frito-Lay	1	92-349-03r	Potato	Release
14-Dec-92	09-Feb-93	Frito-Lay	1	92-349-04r	Potato	Release
15-Dec-92	16-Mar-93	Monsanto	18	92-350-01r	Soybean	Release
16-Dec-92	26-Apr-93	Frito-Lay	1	92-351-01r	Potato	Release
17-Dec-92	27-Jan-93	PetoSeed	11	92-352-01r	Tomato	Release
24-Dec-92	26-Mar-93	Monsanto	15	92-359-01r	Soybean	Release
28-Dec-92	20-Apr-93	Calgene	2	92-363-01r	Rapeseed	Release
28-Dec-92	10-Feb-93	Calgene	8	92-363-02r	Rapeseed	Release
28-Dec-92	08-Apr-93	Calgene	1	92-363-03r	Cotton	Release
28-Dec-92	18-Mar-93	Calgene	3	92-363-04r	Cotton	Release
28-Dec-92	16-Apr-93	Monsanto	38	92-363-05r	Potato	Release
28-Dec-92	14-Apr-93	DeKalb	1	92-363-06r	Corn	Release
30-Dec-92	01-Apr-93	DeKalb	1	92-365-04r	Corn	Release
30-Dec-92	26-Apr-93	Cornell U	1	92-365-07r	Apple	Release
04-Jan-93	27-Apr-93	Monsanto	1	93-004-01r	Potato	Release
04-Jan-93	26-Mar-93	U of California/Davis	1	93-004-02r	Walnut	Release
08-Jan-93	30-Apr-93	Frito-Lay	3	93-008-01r	Potato	Release
11-Jan-93	05-Apr-93	Monsanto	3	93-011-02r	Cotton	Release
11-Jan-93	05-Apr-93	Monsanto	4	93-011-03r	Soybean	Release
11-Jan-93	20-Apr-93	Monsanto	3	93-011-04r	Soybean	Release
11-Jan-93	30-Apr-93	Monsanto	26	93-011-05r	Cotton	Release
12-Jan-93	28-May-93	U of Idaho	1	93-012-01r	Potato	Release
12-Jan-93	03-May-93	Monsanto	1	93-012-02r	Cotton	Release
12-Jan-93	06-Apr-93	Monsanto	17	93-012-03r	Cotton	Release
12-Jan-93	29-Apr-93	Monsanto	2	93-012-05r	Soybean	Release
12-Jan-93	26-Mar-93	Monsanto	3	93-012-06r	Soybean	Release
12-Jan-93	02-Mar-93	Monsanto	2	93-012-07r	Soybean	Release
14-Jan-93	13-Apr-93	Ciba-Geigy	9	93-014-01r	Corn	Release
14-Jan-93	26-Apr-93	Northrup King	22	93-014-03r	Corn	Release
19-Jan-93	14-Apr-93	Pioneer	2	93-019-01r	Corn	Release
19-Jan-93	26-Mar-93	North Carolina State U	1	93-019-03r	Tobacco	Release
21-Jan-93	15-Apr-93	Hoechst-Roussel	13	93-021-10r	Corn	Release
21-Jan-93	22-Apr-93	Hoechst-Roussel	2	93-021-11r	Corn	Release
22-Jan-93	22-Apr-93	Pioneer	1	93-022-02r	Corn	Release
26-Jan-93	22-Apr-93	Monsanto	1	93-026-01r	Soybean	Release
26-Jan-93	14-Apr-93	U of Wisconsin/Madison	1	93-026-03r	Pseudomonas	Release
26-Jan-93	26-May-93	U of California/Berkeley	1	93-026-04r	Pseudomonas	Release
26-Jan-93	14-May-93	Upjohn	3	93-026-05r	Corn	Release
26-Jan-93	26-Mar-93	Pioneer	2	93-026-07r	Corn	Release
26-Jan-93	20-Apr-93	Pioneer	3	93-026-08r	Corn	Release
26-Jan-93	25-Mar-93	U of Florida	1	93-026-09r	Tobacco	Release
26-Jan-93	26-Mar-93	Purdue U	1	93-027-01r	Tomato	Release
29-Jan-93	30-Apr-93	Dow	2	93-029-02r	Corn	Release
02-Feb-93	13-Apr-93	PetoSeed	1	93-033-01r	Tomato	Release
02-Feb-93	26-May-93	Pioneer	1	93-033-02r	Sunflower	Release
03-Feb-93	13-Apr-93	Calgene	89	93-034-01r	Cotton	Release
08-Feb-93	22-Jun-93	U of Wisconsin	1	93-039-02r	Poplar, Spruce	Release
09-Feb-93	30-Apr-93	Ciba-Geigy	1	93-040-02r	Tobacco	Release
10-Feb-93	06-Apr-93	Upjohn	5	93-041-01r	Melon, Squash	Release
10-Feb-93	06-Apr-93	Cargill	1	93-043-02r	Corn	Release

BIOTECHNOLOGY RELEASE PERMITS ISSUED

Date rec'd	Date issued	Institution	Sites	Bp number	Reg article cat	Intro type
10-Feb-93	08-Apr-93	Cargill	1	93-043-03r	Corn	Release
16-Feb-93	13-Apr-93	Upjohn	4	93-047-02r	Soybean	Release
16-Feb-93	29-Apr-93	Upjohn	8	93-047-03r	Soybean	Release
17-Feb-93	04-May-93	American Cyanamid	1	93-048-01r	Tobacco	Release
17-Feb-93	04-May-93	Cargill	2	93-048-02r	Rapeseed	Release
18-Feb-93	04-May-93	U of Idaho	1	93-049-02r	Rapeseed	Release
18-Feb-93	30-Apr-93	North Carolina State U	1	93-049-03r	Tobacco	Release
19-Feb-93	04-May-93	Agritope	1	93-050-01r	Tomato	Release
22-Feb-93	08-Apr-93	Du Pont	6	93-053-01r	Cotton	Release
22-Feb-93	20-May-93	Upjohn	8	93-053-02r	Melon, Squash	Release
22-Feb-93	01-Apr-93	Harris Moran	2	93-053-06r	Melon	Release
23-Feb-93	11-Aug-93	Michigan State U	1	93-054-02r	Agroetis palustris	Release
25-Feb-93	19-May-93	Louisiana State U	1	93-056-02r	Rice	Release
01-Mar-93	14-May-93	Pioneer	1	93-060-02r	Corn	Release
01-Mar-93	08-Apr-93	InterMountain Canola	1	93-060-03r	Rapeseed	Release
04-Mar-93	17-Jun-93	Miles	2	93-063-01r	Tobacco	Release
04-Mar-93	08-Apr-93	Monsanto	2	93-063-04r	Tomato	Release
04-Mar-93	26-May-93	Amer Crystal Sugar	1	93-063-05r	Beet	Release
08-Mar-93	22-Apr-93	Heinz	1	93-067-01r	Tomato	Release
08-Mar-93	13-Apr-93	U of Idaho	1	93-067-02r	Potato	Release
15-Mar-93	12-Jul-93	Upjohn	1	93-074-03r	Cucumber	Release
15-Mar-93	19-Jul-93	Upjohn	1	93-074-07r	Melon	Release
17-Mar-93	18-May-93	Holdens	3	93-076-01r	Corn	Release
17-Mar-93	05-May-93	Holdens	2	93-076-02r	Corn	Release
17-Mar-93	14-May-93	Holdens	1	93-076-03r	Corn	Release
18-Mar-93	22-Apr-93	U of California/Davis	1	93-077-02r	Tomato	Release
18-Mar-93	20-Jul-93	Upjohn	2	93-077-03r	Lettuce	Release
18-Mar-93	05-Apr-93	Pioneer	1	93-077-04r	Corn	Release
19-Mar-93	29-Apr-93	Monsanto	1	93-078-01r	Soybean	Release
26-Mar-93	22-Apr-93	DNA Plant Technology	1	93-085-01r	Tomato	Release
26-Mar-93	20-Jul-93	Upjohn	1	93-085-03r	Squash	Release
29-Mar-93	28-May-93	Louisiana State U	1	93-088-01r	Rice	Release
29-Mar-93	04-Jun-93	U of Wisconsin	1	93-088-02r	Alfalfa	Release
31-Mar-93	14-Jun-93	Hoechst-Roussel	1	93-090-01r	Beet	Release
31-Mar-93	04-Jun-93	Du Pont	2	93-090-02r	Rapeseed	Release
15-Apr-93	04-Jun-93	Michigan State U	1	93-105-01r	Melon	Release
15-Apr-93	12-Jul-93	Florida U	1	93-105-02r	Peanut	Release
15-Apr-93	17-Jun-93	Michigan State U	2	93-105-04r	Melon	Release
15-Apr-93	17-Jun-93	NY Agr Exp Station	2	93-105-06r	Squash	Release
15-Apr-93	18-Jun-93	NY Agr Exp Station	1	93-105-07r	Melon	Release
27-Apr-93	15-Jun-93	Kentucky U	1	93-117-01r	Tobacco	Release
28-Apr-93	12-Jul-93	NY Agr Exp Station	1	93-118-01r	Squash	Release
14-Jun-93	12-Jul-93	Upjohn	1	93-165-01r	Squash	Release
14-Jun-93	12-Aug-93	Upjohn	2	93-165-02r	Squash	Release
14-Jun-93	28-Sep-93	Betaseed	1	93-165-03r	Beet	Release
16-Jun-93	25-Aug-93	U of Hawaii/Manoa	1	93-167-01r	Lettuce	Release
24-Jun-93	02-Jul-93	Calgene	5	93-175-01r	Rapeseed	Release
02-Jul-93	21-Jul-93	Calgene	7	93-183-01r	Rapeseed	Release
09-Jul-93	05-Oct-93	Calgene	2	93-190-01r	Rapeseed	Release
22-Jul-93	05-Aug-93	Calgene	20	93-203-01r	Rapeseed	Release
02-Aug-93	10-Sep-93	PanAmerican Seed	1	93-214-01r	Carrot	Release
09-Sep-93	17-Nov-93	Monsanto	1	93-252-01r	Potato	Release
08-Oct-93	17-Nov-93	Pioneer	1	93-281-01r	Corn	Release
16-Nov-93	04-Mar-94	ARS	4	93-320-01r	Barley	Release
06-Dec-93	16-Feb-94	PetoSeed	1	93-340-02r	Carrot	Release
08-Dec-93	31-Mar-94	ARS	3	93-342-01r	Tomato	Release
17-Dec-93	28-Feb-94	DNA Plant Technology	1	93-351-01r	Pea	Release
30-Dec-93	31-Mar-94	Washington U	1	93-364-01r	Arab. thaliana	Release
06-Jan-94	16-Feb-94	Upjohn	1	94-006-02r	Melon, Squash	Release
08-Feb-94	04-Mar-94	Amer Crystal Sugar	2	94-039-02r	Beet	Release
08-Feb-94	05-Apr-94	Upjohn	5	94-039-04r	Melon, Squash	Release
23-Feb-94	25-Mar-94	Upjohn	3	94-054-01r	Squash	Release
10-Mar-94	29-Mar-94	Michigan State U	2	94-069-01r	Melon	Release

INTEGRATED SYSTEMS ACQUISITION PROJECT

Mr. DURBIN. What is the status of your Integrated Systems Acquisition Project? Please provide details as to current acquisition, funding on hand, and anticipated life cost of the program.

Dr. KING. The ISAP proposals were received on October 14, 1993, with an award date anticipated for the end of FY 1994 or the beginning of FY 1995. The ISAP teams—located in Hyattsville, MD and Ft. Collins, CO—have begun the process of validating and evaluating the proposals. The teams are also studying the impact of the Headquarters Relocation Project's plans on the implementation.

We have begun to develop transition and implementation plans for the Agency. These plans will utilize the findings of the Information Systems Planning process and focus initially on the communications requirements of APHIS.

The current ISAP funding includes a carryover amount of \$1.8 million from FY 1993 and FY 1994 appropriation of \$3.5 million. The total available funding for ISAP in FY 1995 is \$5.3 million.

The anticipated life cost of the program is \$267 million. The current estimated total benefits accrued by the Agency through ISAP remains in excess of \$856 million. The ISAP team is continually reviewing new and existing projects as part of the Benefit/Cost process.

CONTINGENCY FUND

Mr. DURBIN. What is the status of the APHIS Contingency Fund?

Dr. KING. I will provide the information for the record.

[The information follows:]

1993 Carryover	\$2,086,662
1994 Appropriation	4,938,000
	<hr/>
Total available	7,024,662
Fiscal year 1994 approved requests:	
Asian gypsy moth	(3,000,000)
Rabies control/vaccine research	(474,000)
<i>Escherichia coli</i> 0157:H7	(724,000)
Pine shoot beetle	(600,000)
Chrysanthemum white rust	(283,000)
Tropical bont tick	(350,000)
European gypsy moth	(593,350)
Potato diseases	(70,000)
	<hr/>
Balance available	(930,312)

Mr. DURBIN. Please provide a listing of all funding expenditures from the Contingency Fund for fiscal years 1991, 1992, and 1993, and so far in 1994.

Dr. KING. I will provide the information for the record. Any contingency fund balance remaining at the end of the fiscal year carries forward into the next fiscal year.

[The information follows:]

CONTINGENCY FUND

[In thousands of dollars]

Program	Fiscal year 1991 approved releases	Fiscal year 1992 approved releases	Fiscal year 1993 approved releases	Fiscal year 1994 approved releases
Asian gypsy moth				\$3,000
Avian influenza			\$780	
Bovine spongiform encephalopathy	\$487			
Chrysanthemum white rust	170		402	283
Exotic Newcastle disease	189			
E. Coli 0157:H7				724
European gypsy moth	572	\$621	729	593
Potato diseases				70
Pine shoot beetle			635	600
Potato virus Y	516	1,402	752	
Rabies control				474
Salmonella enteritidis		3,366	¹ 166	
Scrapie		2,072		
Screwworm		825	1,575	
Sweetpotato whitefly		298		
Tropical bont tick				350
Tuberculosis	1,202		602	
Total	\$3,136	\$8,584	\$5,641	\$6,094

¹ This \$166,000 is part of the \$3,366,000 released in FY 1992.

HORSE PROTECTION ACT

Mr. DURBIN. The Congress provided APHIS with additional funds in fiscal year 1994 to purchase thermograph machines for use in the horse protection program. What is the status of that purchase?

Dr. KING. APHIS proposes to conduct a pilot program involving the purchase of one, together with the lease of three new machines. Initially, we estimated that \$100,000 would purchase four new machines—\$25,000 per machine—leaving \$20,000 available for training of personnel in the use of the machines and evaluating machine performance. Subsequent market research has revealed that our estimates significantly understated the true cost of these machines in today's market. When purchased new, today's thermograph machines cost an estimated \$55,000 to \$60,000 each.

Because of this situation, we believe a lease-purchase combination option offers the best opportunity for evaluating the machines' potential as an enforcement tool. The plan keeps this component of the program within the FY 1994 appropriations increase of \$120,000 while allowing us to conduct a pilot test of the machines prior to a decision on whether to proceed in the purchase of additional machines with the accompanying capital investment. The availability of additional funds will determine if this project will continue.

Mr. DURBIN. When do you expect the evaluation on the effectiveness of these machines to be complete?

Dr. KING. Training must be provided for selected Veterinary Medical Officers to learn to operate and become familiar with the thermovision machines. Additional training must be provided to the thermovision operators, to teach them how to interpret the results and to differentiate between normal and abnormal conditions and patterns.

We anticipate using the thermovision machines for this year's horse show season which is heaviest during the summer months. When the show season is finished, we shall evaluate the use and effectiveness of the thermovision machines and advise you accordingly.

AIRCRAFT

Mr. DURBIN. For the record, please list all the aircraft in the APHIS inventory, by type, and include the number of hours flown during fiscal years, 1991, 1992, and 1993.

Dr. KING. See the following table.

ID Number	Make	Year	Type	Hours flown		
				Fiscal year—		
				1991	1992	1993
N731EQ	Cessna	1977	A188B	131	278	145
N9664K	Cessna	1983	A188B	141	124	123
N9486G	Cessna	1971	U206E	39	86	190
N9935R	Cessna	1986	U206G	41	166	134
N9583M	Cessna	1978	U206G	141	52	393
N5411X	Cessna	1980	U206G	75	97	246
N25696	Beechcraft	1973	95-B55	52	220	365
N6810S	Beechcraft	1976	58	35	293	419
N726	Piper	1982	PA-18	0	0	513
N734	Arctic T	1984	S1-B2	482	424	160
N742	Piper	1964	PA-18	504	122	234
N744	Piper	1983	PA-18	529	558	685
N746	Piper	1964	PA 18	253	217	115
N751	Piper	1978	PA-18	411	613	629
N752	Piper	1975	PA-18	440	541	567
N796	Hughes	1979	269C	545	610	614
N1099N	Hughes	1980	269C	549	668	588
N53673	Cessna	1977	A188B	7	45	0
N2306	Cessna	1969	U206D	50	39	7
N25698	Beechcraft	1973	B55	0	0	252
N8991Y	Piper	1974	PA-18	0	0	0
N8995Y	Piper	74	19PA-18	0	0	0
N82851	Piper	1974	PA-18	0	0	0

Mr. DURBIN. For the record, how many aircraft and which types have you purchased in each of the past five years?

Dr. KING. See the following table.

[The information follows:]

Year purchased	Make	ID number	Model	Year
1989	Cessna	N5411X	U206	1980
1989	Cessna	N9583M	U206	1978

SCRAPIE

Mr. DURBIN. What is the status of the scrapie control program? What resources are being expended?

Dr. KING. In FY 1993, we established a voluntarily scrapie flock certification program—VSFCP—to reduce the incidence and control the spread of scrapie. Since this program began on October 1, 1992, 60 flocks have been enrolled. In FY 1993, 28 flocks were enrolled and no infected sheep were found in these flocks. In FY 1993, 32 flocks were enrolled as of December 31, 1993.

APHIS is continuing to conduct activities associated with the VSFCP and will intensify efforts to encourage producer participation. This is the first scrapie program that has had the input and support of such a broad cross section of industries, including the sheep industry, allied industries, State animal health officials, APHIS, and other interested parties. The program calls for the gradual development of flocks that are certified to be scrapie and represents a first step toward eradicating scrapie from the United States.

I will provide a table that shows the estimated costs that will be expended in FY 1995 broken out by activists.

[The information follows:]

Estimated fiscal year 1995 cost of Scrapie Certification Program

Activity	Estimated cost
Diagnoses and Epidemiological investigations	\$1,040,633
Support of mission; Texas Investigation Center	569,757
Inspection and monitoring of participating flocks	518,488
Producer education	416,178
Cooperative agreements	320,248
Records and data management	103,696
Total	2,969,000

Mr. DURBIN. For the record, please provide a table showing the expenditures for the scrapie program broken out by indemnity, research, and other for the past three years.

Dr. KING. I'll provide a table that shows the expenditures for the scrapie program broken out by indemnity, research, and other costs for FY 1992, FY 1993, and estimated for FY 1994.

[The information follows:]

SCRAPIE INFORMATION PROGRAM SPENDING

Activity	Fiscal year 1992	Fiscal year 1993	Fiscal year 1994	Total
Indemnity ¹	\$73,095	\$1,016,000	\$1,089,395
Research	320,152	184,498	\$246,000	750,650
Other	561,435	562,202	2,754,000	3,877,637
Total	954,682	1,763,000	3,000,000	5,717,682

¹ Scrapie indemnities were funded out of the contingency fund in FY 1993.

Dr. DURBIN. It is my understanding that many producers declined to participate in the scrapie indemnity program because of the record keeping requirements placed on participants. Is this correct?

Dr. KING. These requirements may have been one reason some producers declined to participate. The indemnity regulations required that owners of indemnified flocks participate in the flock certification program, which calls for documentation of new animal purchases, flock depopulations, actions upon animal deaths, and submission of diagnostic samples. Basically, the indemnity program requires flock owners to identify the origin of their animals. This will provide us with the information necessary for an epidemiological traceback or investigation, if such action is warranted. The scrapie indemnity program was developed by the Scrapie Negotiated Rulemaking Advisory Committee, which consisted of representatives from APHIS, sheep breeding organizations, sheep in-

dustries, and stakeholders. In developing this program, the Committee felt that these recordkeeping requirements were not overly stringent and were essential to the integrity of the program because they would ensure that the program could account for every animal in a flock. Other reasons why producers decided not to participate in the indemnity program may have been that they thought it too costly to replace their stock or they did not recognize the extent of scrapie in their flocks.

BUILDINGS AND FACILITIES

Mr. DURBIN. Does APHIS have a backlog of buildings and maintenance problems at its facilities? For the record, please provide a list of maintenance backlog work and the appropriate cost to correct each.

Dr. KING. See the following table.

<i>Project and Location</i>	<i>Estimated cost</i>
Convert:	
Electrical heat to propane, Rock Tavern, NY	\$30,000
Repair:	
Screening of quaran. bldgs., Rock Tavern, NY	20,000
Roof bldg. 580, Beltsville, MD	10,000
Roof, Phoenix, AZ	20,000
Incinerators, Brownsville, TX	15,000
Concrete floors, Waimanalo, HI	98,000
Replace:	
Scrubbers, Key West, FL	2,600,000
Incinerators, Rock Tavern, NY	1,500,000
Incinerators, Haiku, HI	50,000
Sewer line bldg. 6&16, Gulfport, MS	4,000
Ductwork/filter box, Waimanalo, HI	15,000
Boilers, Pocatello ID	25,000
Grain mixer, Pocatello, ID	150,000
Grain cleaner, Pocatello, ID	60,000
Water pipes, Pocatello, ID	300,000
Coyote kennels, Logan, UT	30,000
A/C systems in Bldg. 2&5, Gulfport, MS	100,000
Install:	
Standby generators, Ames, IA	295,000
Drop ceiling, Phoenix, AZ	4,000
Flooring, Phoenix, AZ	2,000
Chiller system, Edinburg, TX	30,000
Emergency generator, Gulfport, MS	250,000
Two power sprayers, Waimanalo, HI	10,000
Acoustical barriers, Waimanalo, HI	4,600
Chain link fence, Twin Falls, ID	5,000
Incinerator, Albuquerque, NM	30,000
New aviary, Sandusky, OH	30,000
New cormorant holding facility, Starkville, MS	152,000
Fumigation chamber, Gulfport, MS	6,000
New partition, Phoenix, AZ	4,000
Water treatment equipment, Niles, MI	6,000
Entrance vestibule, Niles, MI	10,000
New animal building, Olympia, WA	34,000
Renovate:	
Addition to bird building Miami, FL	70,000
Training office, Gulfport, MS	200,000
Upgrade:	
Ventilation system, Pocatello, ID	35,000
Miscellaneous:	
Regrade driveway, Sweetgrass, MT	150,000
Outside fencing, Sweetgrass, MT	50,000
Enclose mezzanine, Waimanalo, HI	11,000

POTATO VIRUS Y

Mr. DURBIN. What work is being carried out by APHIS with regard to the potato virus Y?

Dr. KING. APHIS regulates PVY-N through the United States Canada Management Plan. This plan regulates PVY-N by detecting early generations of infected potatoes and disallowing them to be sold as seed potatoes. The rule to remove those portions of the regulations that dealt with PVY-N in Canada and the United States was published December 20, 1993. Currently, the affected potato growing States and producers regulate PVY-N through potato seed certification.

Mr. DURBIN. How much is being spent on this activity and where?

Dr. KING. APHIS will provide up to \$70,000 to the State of Maine for seed potato testing. Seed potatoes would be tested for potato diseases such as PVY-N and late blight, reducing the risk of spread through seed potatoes.

REINVENTION LABORATORIES

Mr. DURBIN. You indicate that you have selected eight work sites for "reinvention laboratories." Describe this experiment. Where are the eight sites?

Dr. KING. I would be happy to describe this experiment. Under the National Performance Review [NPR], our Agency is participating in "reinventing government" through eight reinvention laboratories. I'll provide a brief description of each laboratory's involvement and the laboratory's location for the record.

[The information follows:]

--Field Servicing Office--FSO--, Minneapolis, MN - FSO is participating as a reinvention laboratory by streamlining internal procurement and leasing procedures and implementing a set of waivers and exceptions to the General Services Administration--GSA--rules. FSO, GSA, and USDA's Office of Operations are working as partners in this reinvention lab.

--Program and Policy Development--PPD--, Hyattsville, MD - PPD's Regulatory Analysis and Development Staff is seeking review waivers of selected minor, routine, and non-controversial rules. Benefits would include reduced delays in rulemaking and staff resources, improved quality of regulatory management, and greater responsiveness to USDA and industry customers.

--Veterinary Services, Hyattsville, MD and National Veterinary Services Laboratories--NVSL--Ames, IA - VS charges user fees for veterinary diagnostics and import/export animal services. As a reinvention laboratory, NVSL has implemented a more customer-oriented billing and collections system. By May 1994, computer technology will be available to allow for consolidation of bills so that our customers will receive one bill for all services, including quarantine, permits, tests, and reagents. We are also working to establish a credit card system to enable NVSL customers to pay for services via a charge card.

--National Animal Health Monitoring and Surveillance--NAHMS--Ft. Collins, CO - NAHMS proposes to initiate a preharvest pathogen reduction program involving on-farm interventions to reduce pathogen risks; improved dissemination of the latest information on safe production practices; and establishment of a new partnership among public and private animal health professionals.

--Plant Protection and Quarantine Southeastern Regional Office--SER--, Gulfport, MS - The SER office proposes to make office operations more mission-driven and decentralized by delegating authority and responsibility to State and work unit level managers, and by forming collaborative teams with States and industry.

--Equal Opportunity and Civil Rights--EOCR--, Washington, D.C. - The Agency's EOCR staff is involved with expediting the process of discrimination complaints through initiation of a new, less time-consuming approach to investigative fact-finding conferences, and an expansion of the Alternative Dispute Resolution process. This pilot is currently operating at the Departmental level, and is under assessment at this time.

--Plant Protection and Quarantine, Port of Miami, Miami, FL - PPQ's inspection operation at the Port of Miami is piloting the use of self-directed work teams to enable APHIS employees to better accomplish its mission. They do this by continually identifying and improving procedures and rules that they find cumbersome and anti-productive.

--International Services--IS--, Hyattsville, MD - IS is seeking to apply the principles of total quality management to improve customer satisfaction, productivity, personnel retention, and staff morale. To do this, the lab is using process action teams to improve specific administrative systems and emphasizing a customer-oriented philosophy among headquarters employees to improve customer service.

DETECTOR DOGS

Mr. DURBIN. And my how many Beagle dogs?

Dr. KING. We are going to move from 30 teams to 60 within two years. And they are very popular.

Mr. DURBIN. They are great. Maybe you could provide details for the record along with what you spend on the program.

Dr. KING. They do a good job. I'll be glad to get that for you.

[The information follows:]

Detector dog teams

<i>Location</i>	<i>Number of teams</i>
Atlanta, GA	1
Orlando, FL	1
San Juan, PR	1
Newark, NJ	2
Oakland, CA	1
Detroit, MI	1
Philadelphia, PA	1
Houston, TX	1
Miami, FL	4
Los Angeles, CA	2
San Francisco, CA	5
JFK, NY	7
Boston, MA	1
Chicago, IL	2
Seattle, WA	1
Charlotte, NC	1
Dallas, TX	1
Dulles, DC	1
Bangor, ME	1
Honolulu, HI	4
Total	39

For support of detector dog teams in the AQI program, APHIS spent \$2,555,150 in FY 1992 and \$2,985,200 in FY 1993. The Agency will spend approximately \$3,253,868 in FY 1994.

Mr. DURBIN. I had an opportunity to see them at work. And we should all be blessed with those types of colleagues. Mr. Skeen. [Laughter.]

USER FEE

Mr. SKEEN. There is just no respect. We are going to halve the personnel, human personnel, and we are going to double the dogs. That is pretty good. I think that we are on the right track.

Thank you, Mr. Chairman.

And once again, I am delighted to be with you here this morning, and to hear your testimony. A lot of the topics that we have discussed this morning were very close to my interest and my heart, especially the screwworm program. If you have ever seen the drastic differentiation in the way that it was handled after the program was initiated, you would not have this rather ridiculous idea that because it has a funny name, that it was not an effective program. It is one of the most effective programs that I have ever witnessed in my life.

Because we used to spend about 40 or 50 percent of our time in the livestock business on the screwworms, particularly in the summertime. And particularly after marking lambs or castrating calves, and things like that. Today it is almost unheard of.

But I will tell you one thing. If you have ever seen a screwworm case over there, you have lost your taste for rice pudding. I just ruined the whole entree. That used to be a favorite around ranches.

I wanted to ask you a question in connection with the user fees first of all, because we have had a serious problem with the cattle crossings at Santa Teresa in southern New Mexico. Ranchers have experienced confusion and frustration, because they just did not understand the program. And I think that we helped to alleviate some of that program here recently. Because I finally got the cattle growers and the APHIS people together in our office in Las Cruces, and they had a meeting of the minds.

They went out to the parking lot, and nobody was throwing a punch or anything. But I think that they got down to the bare middle of what the problems were, and are working them out. I am amazed though.

Are all of these user fee funds held? Because there is no mechanism to transfer them to the agency. That is one of my understandings.

Is this the case, that legislatively we do not have the mechanism to move those monies?

Mr. SHEA. Mr. Skeen, these fees are different from the agricultural quarantine inspection fees. The AQI fees are limited by an annual appropriation, as requested by the agency. But the user fees for the Santa Teresa crossing and similar activities are not.

Mr. SKEEN. They can be put into use by the agency?

Mr. SHEA. Yes.

ANIMAL DAMAGE CONTROL

Mr. SKEEN. But we have these ridiculous problems arise, because some of the legislative bars to moving funds from one to the other as far as Treasury is concerned. I did not know if that was a problem or not.

Let us talk about the animal damage control program. We are having a very difficult time in the ranching industry, because it is politically unpopular to kill any kind of an animal. And we understand that. But we had an ADC program that was designed to take care of critical instances of livestock depredation, with airplanes, cyanide guns, and the rest of it.

Somewhere along the line, we have lost the picture, or we do not get an accurate feeling for exactly how these animal damage control programs work. They are not programs that just kill off animals irresponsibly or anything like that, particularly the coyotes. They are actually killing off predators that are in the killing fields and killing daily, nightly, or whatever.

We have lost a lot of that funding, particularly in the aircraft operation end of thing, which is the one that I think is taking care of those critical situations where you have got a killing predator loose in a herd or a flock.

Of course, we operate on an open range. What do we need to do to get this program back on track. We are trying to cover the cost of operating the plane with another user fee idea. The ranchers are paying for the operations of the aircraft in a critical killing instance, but it is not working. It is just too expensive. It is \$78 an

hour or something of that kind of fee. It takes usually about four or five hours of flying time to clean up a situation.

Dr. KING. We are trying to look at short-term strategies and long-term strategies. Let me talk a little bit about long-term strategies and we will come back to more specifics.

Mr. SKEEN. I would like to hear because I think it is time we got together with these people who are so concerned about animal protection and come to some reasonable solution. It is the same situation we have got with the so-called pork busters and the ludites which we have referred to here this morning. It is just a total misunderstanding, so I would be very interested in some kind of a dialogue that drew these two disparate groups together.

Dr. KING. Our long-term strategy is going to focus on research and new findings such as that being done on immuno-contraception for white-tail deer, a population that is burgeoning with all kinds of public problems. Black birds, birds that are—

Mr. SKEEN. Sandhill cranes.

Dr. KING. Exactly. And on and on. And these populations are increasing. So the long-term strategy has to be focused on better research, especially in immuno-contraception to cut down on populations.

Mr. SKEEN. Control the population.

Dr. KING. That is right. Our work at the Denver Wildlife Research Center is very critical to controlling wildlife population. For example, this year about 55 percent of those funds were in non-lethal areas, and will eventually move up to 65 percent, to find improved non-lethal methodologies for a long-term program. Short term, I think it is a little more difficult as budgets contract. Our ability to work, and I think you put your finger on it, with local and State officials, fish and wildlife officials, and others to come together with an integrated program is what is necessary. We must try to work with each other as best we can. ADC is really an integrated pest management program. As we look at those programs, we look at a variety of mechanisms to cut and control populations. Some are lethal, some are not. So there is a lot of predecisional analysis that goes on before decisions are made in terms of selecting the right methodology.

Mr. SKEEN. Well, it is a critical situation and I do not mean to overemphasize it. I come from one aspect of the industry and I want to see the other side as well because we do not like to kill just for killing's sake. That is not the program at all. We want to also protect the species and all the rest, the ferrets and the rest of these things. And indiscriminate killing is just not in the make-up of most ranch operators or livestock operators. Their idea is to propagate their own crops the best they can, but then leave the flora and the fauna and the rest of the things as they were, in as good a shape as possible. But we have had these programs and we have become dependent on them. And now with the retraction of some of the services over there, it has been very, very difficult.

Dr. KING. I would like to make one other comment.

Mr. SKEEN. Yes.

AQUACULTURE

Dr. KING. A new line item is proposed in this budget, a small one albeit, but a new line item and that is in aquaculture.

Mr. SKEEN. Aquaculture?

Dr. KING. Yes. And the bulk of the funding is to set up programs to control a depredation of birds that are involved in limiting catfish production and other fish. So this is a new program. We will have four new wildlife biologists placed in strategic locations to work with industry to reduce the burden of depredation of these birds on the domestic fish producing industry.

Mr. SKEEN. Well, we found that we had a number of problems with farmers and the sandhill cranes in the Bosque del Apache, south of Albuquerque. We organized a meeting and it worked out to the satisfaction of everyone including the farmers who were complaining about the tremendous loss in crops and so forth. We changed the hunting setup a little bit and it worked out. This is the kind of approach I would like to see us do rather than sitting there lobbing grenades at each other and we are not getting anywhere.

Let me ask you about the environmental impact statement then. What is the status of the programmatic environmental impact statement for APHIS that was due for final publication and record of decision? And what program modifications need to be made to implement the ADC's new programmatic EIS?

Dr. KING. The programmatic EIS is in the final throes of review. As a matter of fact, we have sent out a final document to those who worked on it as well as affected industries. So we are in, as I said, the final few weeks of reviewing it. It underwent several modifications because of input from many different groups. I think it has become a good document. And once its notice of availability is published in the Federal Register, then there will be a minimum of 30 days or longer before the record of decision is made on the document. So it is in the final stages of clearance.

Mr. SKEEN. Do you have a date that you think that it will be completed?

Ms. JENSEN. I would hope we are talking just a few weeks.

Mr. SKEEN. A few weeks, okay.

Ms. JENSEN. If that gives you a good sense of timing.

Mr. SKEEN. What progress have you made in ADC in assuming the National Environmental Policy Act—NEPA—a responsibility on the Forest Service lands and how will this affect ADC's responsibility on BLM land?

Dr. KING. Well, we are reviewing a new memorandum of understanding to work on BLM lands.

Mr. SKEEN. With BLM?

Dr. KING. Yes.

Mr. SKEEN. Mr. Babbott needs some help.

Dr. KING. Once that is done, and it is not accomplished yet, but we are working through that, it would enable APHIS to do the environmental assessments or environmental impact statements for BLM, land. And so it is pulled together into one agency with the expertise to get the job done.

Mr. SKEEN. Well, you are going to wind up with most of the responsibility?

Dr. KING. It may very well be that way, the way this MOU is going, yes.

Mr. SKEEN. Does it require more personnel?

Dr. KING. It may require more funding. We have personnel on board—

Mr. SKEEN. Who can handle it?

Dr. KING [continuing]. With the expertise to do the job, but certainly it will take a lot of our resources to do the job.

Mr. SKEEN. Beagles cannot handle it. [Laughter.]

OROBANCHE RAMOSA

Mr. SKEEN. Please provide a brief history of APHIS' work in Texas on the *Orobanche ramosa* Eradication Project, including problems caused by this noxious weed, length of the project, total funds spent on the project, and progress in eradicating this plant.

Dr. KING. *Orobanche ramosa* was first discovered in Karnes County, Texas, in March 1981. *Orobanche ramosa* is an obligate parasite that infests broadleaf plants. Heavy infestations of *Orobanche ramosa* could cause total crop failure. This perennial weed competes with and reduces the yields of various crops including tobacco, tomatoes, melons, celery, sunflowers, safflowers, carrots, cabbage, eggplant, potatoes, turnips, clovers, and grapes. A Federal eradication program was initiated in 1983. APHIS concluded that an eradication program was feasible in Texas, whereas, a program in California was not. California is conducting a State suppression/containment program. The cost of the program has ranged between \$65,000 and \$100,000 per year. Due to the owners resistance to allow APHIS personnel onto their land, APHIS has not been able to eradicate this weed and will terminate the program by the end of fiscal year 1994.

Mr. SKEEN. What was APHIS' original goal when the *Orobanche ramosa* Eradication Project was initiated? Has APHIS achieved its goal?

Dr. KING. The goal of the *Orobanche ramosa* Eradication Project was to eradicate this weed from all the infested areas of Texas. Due to inaccessibility to private land, APHIS was not able to accomplish its goal.

Mr. SKEEN. What must still be accomplished to eradicate *Orobanche ramosa* in Texas?

Dr. KING. APHIS would need to gain access to the remaining infested areas to accomplish eradication and complete the program.

Mr. SKEEN. Has APHIS included any funds in its proposed FY 95 budget for the *Orobanche ramosa* project?

Dr. KING. No. APHIS decided to terminate the program after FY 1994.

Mr. SKEEN. If no funds are available to complete the *Orobanche ramosa* Eradication Project, what will happen with the future spread of this plant?

Dr. KING. We would rely on private ranchers to control weed spread.

Mr. SKEEN. Has APHIS contracted or entered into an agreement with any land owner in the infested area to help eradicate or con-

trol *Orobanche ramosa*? If so, what were the terms of the contract, what work was conducted by the land owner, and what has been the result of this work? Did the property owners allow APHIS access to the property to monitor the work of the contractor? Is this a standard arrangement between APHIS and property owners?

Dr. KING. Yes. Due to the resistance of land owners to allow APHIS personnel onto their land, APHIS entered in an agreement with two land owners, to perform eradication activities within their property boundaries. Under these agreements, the Agency hired the land owners as intermittent employees to survey, map, rouge, and treat their properties. The owners reported their progress to APHIS. So far, eradication has not been accomplished on either property and APHIS decided to terminate the program. This type of agreement is unusual and was driven by the owners resistance to give right-of-access to APHIS into their land.

Mr. SKEEN. Has APHIS exercised all its options to enter private property for the purpose of eradicating *Orobanche ramosa*?

Dr. KING. Yes. APHIS worked with State officials and cooperators to gain right-of-access to private property and complete eradication. Right-of-access to private land was never gained.

IMPORTED FIRE ANT

Mr. SKEEN. What States currently help APHIS enforce the Federal Imported Fire Ant Quarantine?

Dr. KING. We have cooperative agreements with the following States: Alabama, Arkansas, Arizona, California, Florida, Georgia, Louisiana, Mississippi, North Carolina, New Mexico, Nevada, Oklahoma, South Carolina, Tennessee, and Texas.

Mr. SKEEN. How would APHIS' proposed FY 95 budget impact the current cooperative agreements with the States to enforce the Federal Imported Fire Ant Quarantine?

Dr. KING. APHIS will no longer make funds available to States for survey and regulatory enforcement in generally infested areas.

Mr. SKEEN. If APHIS does not provide the States funds to enforce the Federal Imported Fire Ant Quarantine, who will then be responsible for enforcement and how will enforcement be carried out?

Dr. KING. All regulatory and survey activities would be conducted by the States. APHIS will continue to evaluate the efficacy of regulatory treatments for preventing further artificial spread of the Imported Fire Ant—IFA—under the plant methods development line item.

Mr. SKEEN. In previous years, APHIS has testified that if Federal funding to assist states in enforcing the federal quarantine was eliminated it would increase the likelihood of the fire ant spreading into uninfested areas. Will this still be the case in FY 95? If so, how?

Dr. KING. IFA is spreading at a slow pace. Twenty-nine new counties reported infestations in FY 1993. Small isolated outbreaks continue to occur in previously uninfested areas. Many of these can be traced back to movement of noncertified regulated articles.

Mr. SKEEN. How are APHIS funds being used by the States to prevent the spread of the imported fire ant?

Dr. KING. APHIS funds are used by States to conduct surveys to determine new areas that need to be regulated, and provide inspection and certification services at regulated establishments for the movement of nursery stock and other regulated articles.

Mr. SKEEN. If the States can not offset the proposed reduction in federal funding for the fire ant quarantine program, what is the potential impact on the interstate shipment of nursery and other agricultural products?

Dr. KING. The impact on the interstate shipment of nursery and other agricultural products would be minimal. If Federal quarantine were revoked, the States would impose and enforce quarantines.

Mr. SKEEN. What other fire ant activities will be eliminated or curtailed under the proposed FY 95 budget?

Dr. KING. APHIS will no longer make funds available to States on a 50/50 basis for control projects in generally infested areas. However, since 1985, the Agency has not received any requests from States for cooperative treatment programs, and many States have proven themselves able to successfully eradicate small isolated infestations outside the regulated area.

Mr. SKEEN. What is APHIS currently doing to coordinate with other Federal agencies to find additional control methods or a possible eradication method for the imported fire ant?

Dr. KING. The IFA station in Gulfport, Mississippi, coordinates technology development to support the Federal fire ant quarantine. This station tests Award© and other products annually in a cooperative effort with the registrants to develop more cost-effective methods of combatting fire ants. APHIS will continue to work with industry and to conduct methods development laboratory trials looking at promising new control methods. APHIS will continue to work with the Agricultural Research Service to screen and develop promising new chemicals and biocontrol agents. APHIS also provides technical assistance and supports research at academic institutions such as the University of Arkansas and Texas Tech University.

Mr. SKEEN. Is there a formal process currently in use to facilitate the coordination of these activities?

Dr. KING. Yes. APHIS is a member of the IFA Technical Work Group. This group meets periodically each year to collect input from industry and State cooperators, determine the needs of the program, and coordinate research and methods development. Other members of the group include: the Agricultural Research Service, Environmental Protection Agency, and our State cooperators. Industry and researchers are also actively involved.

BOLL WEEVIL

Mr. SKEEN. What is the funding request in APHIS' FY 95 proposed budget for the boll weevil eradication program? Please provide specific information on how funds would be used?

Dr. KING. APHIS requests \$13.1 million in the FY 95 proposed budget for the boll weevil eradication program. The Agency plans to use \$880,000 for the Southwest Eradication program, including \$800,000 for post-eradication activities in Arizona and California and \$80,000 for eradication activities in Caborca, Mexico. An addi-

tional \$1.02 million would be used in the Central Eradication and Suppression program in Texas. In addition, \$11.2 million would be used in the Southeast Eradication program. The Southeast Eradication program is composed of three types of activities: first, eradication activities, which include 410,000 acres in central and north Alabama, central Georgia, northeast Mississippi, and central Tennessee. Second, maintenance/confirmation activities, which include 720,000 acres of areas that have not been declared eradicated in south Alabama, Florida, and Georgia. Third, post-eradication activities, which include 650,000 acres in North Carolina, South Carolina, and Virginia.

Mr. SKEEN. What does APHIS calculate is the funding level needed in FY 95 to continue current boll weevil programs and initiate additional programs that are ready to begin in FY 95?

Dr. KING. In FY 1995, APHIS would need \$36 million to continue current boll weevil programs and initiate the accelerated expansion program proposed by the industry. Under the accelerated eradication program, the boll weevil would be eradicated 14 years sooner than the initial plan.

Mr. SKEEN. Thank you very much for your responses.

Mr. Chairman, thank you.

Mr. DURBIN. Thank you, Mr. Skeen.

Mr. Thornton?

Mr. THORNTON. Thank you, Mr. Chairman, and let me add my endorsement to your concerns about those who use funny sounding names to try to ridicule programs that are very important to consumers and to all people in America. They save us money, improve the quality of our food, and I really share your views about the ludites.

Mr. Skeen, it is always a pleasure and a little bit of a discouragement to follow you because you ask exactly the questions that need to be asked and I do want to follow along on your line of questioning a bit. I want to thank you.

Mr. SKEEN. You can do anything you want with my questions.

AQUACULTURE

Mr. THORNTON. Very good. Thank you, sir.

With regard to the control of animal populations, you elicited the concern that I wanted to bring to your attention about aquaculture and about not only the problems associated with birds, but also with diseases, pathogens that affect aquaculture. Are you looking at that?

Dr. KING. Yes, sir, and it is an excellent point for an industry that is really starting to expand and grow. We are in the process of developing coordination with that industry like we have with other livestock industries.

The line item that I talked about with Congressman Skeen also has the beginnings of a program for veterinary services as part of APHIS to be engaged in certification and also in looking at preventing exports and imports of diseases and pests of fish and aquaculture.

We are also involved in vaccines for the aquaculture industry at our laboratory in Ames, Iowa. So we also see that as an expanding role and a very important role.

Mr. THORNTON. The laboratory at Ames, Iowa, is a very good one. I do want to call to your attention because—it is perhaps parochial, but also a personal interest of mine. While President of the University of Arkansas, I served for a time as Chancellor of our historically black campus, the University of Arkansas at Pine Bluff. And that institution has the responsibility for all aquaculture research that is conducted in the State of Arkansas. They have some splendid facilities on the campus and if you have not made contact with them with respect to this new area of study, I think it would be a good thing for you to do. You will find that they are doing quite well with traditional sources of funding and perhaps there might be a linkage there.

Dr. KING. I would be glad to contact them.

FIRE ANTS

Mr. THORNTON. We are concerned in Arkansas, also, about the migration of the fire ants which continues to proceed unchecked. The little wasps without wings are developing the ability to move into colder climates. Are you researching that? Are you finding any way of controlling the fire ant problem?

Dr. KING. Unfortunately, not very good news. We are not engaged in the research. That would be Agricultural Research Service or Cooperative State Research Service engaged in those activities. Right now there is no registered treatment available for that pest on agricultural lands.

Our contribution has been to try to prevent the spread, especially working through certifications at nurseries to prevent the spread from areas where it currently is into new areas.

We are also working with companies to look at new registered products. There are some new products for private use, but they are still not approved for agricultural lands. Telstar is one. There is also a new product that shows some promise called Affirm, that targets the queen ant. ARS is working on attractants that could be used in combination with pesticides. But the program right now really lacks a good control mechanism and certainly nothing that has been environmentally cleared, so we are somewhat frustrated and limited in what we can do.

Mr. THORNTON. Well, I pledge my full support in defending you against the pork-busters, if you are able to come up with some genetic or any other means of controlling this particular pest.

I also noticed your program for controlling the release of genetically modified organisms. And it seems to me that there may be some fears there that ought to be abated. I can recall some genetically altered organisms that went into use in the early part of this century. Not at the very beginning because I was not around to recall that, but for example, hybrid corn. Genetic alteration of plants has been going on for a long time, has it not, sir?

Dr. KING. Yes, it has. This process certainly speeds that up.

Mr. THORNTON. Oh, it does. It is a tool. It is a tool for achieving what required long years of selective breeding and in some instances even crossing genetic barriers, transgenetic. But tell me about your release protocols. Are you very cautious to assure that any genetically modified organism are released first in a controlled

environment so that you can evaluate the results of those releases before approving them for field tests?

Dr. KING. Yes. I am very proud of what APHIS has done in that regard. We have good expertise. This is an area that we have taken a conservative approach, but one that we also know that new industries are moving forward and we also want to support and facilitate those new industries as well. So it is, I believe, a good balance. We started a few years back with five potential products; we now have 141 out there waiting for approval.

We have also done a lot of work through risk analysis and risk assessment. We understand half-a-dozen of these commodities very well because of the work that we have done. We do not have to go through the same process over and over again with different commodities. We will take the information that we have and actually expedite the process of clearance based on our knowledge up to this date.

Mr. THORNTON. Thank you very much.

Mr. Chairman, I yield back.

Mr. DURBIN. Mr. Peterson.

Mr. PETERSON. Thank you, Mr. Chairman. I will not be able to speak very long obviously.

USER FEES

I want to go back to the cap on these user fees. We imposed it because you asked for it. I know you do have authorization to go over 10 percent above that cap or I assume the AQI—

Dr. KING. For AQI user fees, that is correct.

Mr. PETERSON. And I think I heard you say that you were going to ask for some additional user fee. If you are not already using what you already have, how is it then justified that we collect more user fees?

Dr. KING. I think the point is that if we did not have that spending limitation, we could provide a lot more resources for services. For example, in Miami, I think that more resources could be used. So the spending limit makes it difficult to move ahead.

Mr. PETERSON. Well, on that point, in Miami you collect about \$14 million in user fees and you only spend \$6 million if my numbers are correct.

Mr. SHEA. Mr. Peterson, we collect the money based on a national system. And for that reason it is hard to pinpoint collections by ports and spending by ports. We know what we are spending by port, but the collections can vary because the fee for passengers is collected at the time the ticket is bought, so we cannot be sure where the fees are generated. But the fees are based on an annual nationwide basis rather than on a port-by-port basis. And when Dr. King spoke earlier of fees, we were speaking of access to the fees we have already collected. We do not intend to propose any new fees at all.

Mr. PETERSON. All right. So you are asking us today to remove the cap.

Mr. SHEA. Yes.

Mr. PETERSON. And that is contained in your 1995 request.

Mr. SHEA. Yes, it is.

MIAMI INSPECTION

Mr. PETERSON. Now, back to Miami. Last year in two separate paragraphs in the appropriation report language, we made special note of the fact that there were problems in Miami. Can you tell me what you have done to improve the circumstance in Miami since October of 1993 to date.

Dr. KING. In 1993, we added three new inspectors and two dog teams. This year we added two new technicians and another dog team.

Mr. PETERSON. Have you assessed the possibility of going to a 24-hour operation at Miami which is, by your own report, if not the busiest, the second busiest cargo airport perhaps in the world.

Dr. KING. We are looking at that. It is not without some problems, but we are looking at it. Part of it would be our ability to access the fees already collected that are in this separate account. That would be helpful. But we would have to also visit with the unions to talk about reimbursable overtime and how we could get that done. I think the main thing is our concern about the health and safety of those people. They work a tremendous number of hours. We have to rotate them—

Mr. PETERSON. I know. I am not saying you keep the same number of people. If you go 24 hours, clearly you need more people and as I understand it you have 77 people there now and even to talk about doing anything to improve, you need at least another 15.

Dr. KING. And they are rotated between those three different functions as I talked about.

Mr. PETERSON. Right. Let us then look at what you have got out there. You are dealing with the second busiest airport, I am going to assume the second busiest—I think it is actually the first—cargo airport in the world and it has not the same services as much less activity airports elsewhere in the United States. And so you have resources out there that seem to me to be able to be moved to where you need them. Is that an option?

Dr. KING. It is an option on special occasions, especially when cut flowers would come through during peak times. So that is an option that we would look at certainly.

Secondly, somebody asked me about temporary people. Well, that is not really the solution. The people have to be trained. They must be highly skilled to be put in a position like that. I think we can come to a meeting of the minds on this with this 1995 appropriation in terms of our ability to get more resources for that port, and I would be willing to try that on a pilot project on a 24-hour basis under those circumstances.

Mr. PETERSON. Well, I am happy to hear that because I think we are at a circumstance here that we are leaving ourselves open. If the product is coming in and one of your initiatives here in your statement was that you were going to focus on your customers, well, your customers are not being served. And then ultimately our citizenry is not because if this cargo is not being inspected or if the perishables sit on the dock, you have other potential contaminations. I think the problem is much bigger than what we have discussed here today. So I would like to strongly request you to look at this Miami question and look at the absolute needs and begin

to address them. I do not think we have addressed them aggressively based on the kind of signals that we intended to send last year. The message may not have gotten across, but it is something that I think we stand very strongly on here and by virtue of the Chairman's comments as well. I end my questioning, but please look into my concerns Okay?

Dr. KING. Yes.

Mr. PETERSON. Thank you very much.

Thank you, Mr. Chairman.

Mr. DURBIN. Thank you, Mr. Peterson.

Mr. Pastor?

Mr. PASTOR. Thank you, Mr. Chairman, and good morning.

ANIMAL DAMAGE CONTROL

Let me continue with some questioning on the animal damage control program. What is the reduction in funds that you anticipate in fiscal year 1995?

Dr. KING. Approximately \$2.6 million in operations and \$329,000 in methods development.

Mr. PASTOR. Now in your response to Congressman Skeen you said you had a short-term solution and a long-term solution. Could you go into some detail again about the short term and the long term goals? Start with the short term and how this reduction fits in.

Dr. KING. Well, we were faced with some very tough choices. And those tough choices obviously translate into some reductions where we are going to have to do less and that means that somebody else is going to have to pick up more. I do not think that is exactly what some folks would want to hear but I think that is kind of the point we have reached.

Mr. PASTOR. That is the short term.

Dr. KING. The short term. The long term still has to focus on research, breakthroughs, immuno-contraception, new repellents, new electrical scaring devices, et cetera, to try to control these populations in ways that do a better job than we do today.

Mr. PASTOR. In Arizona we are concerned about livestock, sheep, et cetera. In my conversations with the Arizona Farm Bureau, the Arizona Department of Agriculture, Game and Fish Commission, I have heard them say, "Those reductions we cannot pick up because of scarce resources at our level. We just cannot pick them up."

Are we abandoning the whole program? Is that what you are basically telling me?

Dr. KING. No. We are definitely not abandoning the program.

Mr. PASTOR. Okay. Tell how we are not.

Dr. KING. Well, we still have over \$23 million in the program and it is a cooperative program, so we are not abandoning it. I appreciate your concern. We are at the point where we have to make tough choices. And we are making tough choices. The one thing in the short term that bothers me is that as producers themselves take on more and more of a role, we worry about what kinds of methods will be used. And the idea of a State-Federal cooperative role where we have environmental impact statements and environmental assessments, et cetera, to really make good decisions on these things tend to drop back if people simply go out there and

do things on their own. So we will just have to work more closely with our cooperators and do a better job of prioritizing what our needs are in the different States.

I will also tell you that we allow the State and local officials to make decisions. We do not try to sit here in Washington and tell them where reductions should be taken. They have to be done at the local level where problem solving is best done.

Mr. PASTOR. There is a concern at least in Arizona and I am sure throughout the western States that a reduction in this particular program will cause serious problems.

SWEET POTATO WHITEFLY

Let me go into the sweet potato whitefly research. How much are you proposing to dedicate to this activity?

Dr. KING. In 1994, I believe it was about \$3.5 million in sweet potato whitefly. And that really was in cooperation with State, and industry, and we developed an integrated program within the Department of Agriculture, including ARS and CSRS, to look at how to fit research in with actual operations.

Mr. PASTOR. What is your 1995 request?

Dr. KING. The 1995 request is that we would zero out that line item. We request \$500,000, split between biological control and plant program methods development to continue with looking at biological control agents and the potential release.

Mr. PASTOR. Yesterday, we heard testimony from Congresswoman Thurmond of Florida. She was telling us that Florida is seeing the beginnings of a sweet potato whitefly infestation which is affecting tomatoes. She was concerned that sufficient research needs to be conducted to help ensure this pest could at least be controlled.

I have to tell you that Congressman de la Garza is very concerned about the whitefly problems they are having in Texas, and my producers in Yuma, right now, are having problems with the whitefly affecting the spring melon crop. Come summer, it is going to affect all melons, both cantaloupe and watermelon. It is a problem that probably started somewhere in California and then moved onto the western States. Now it is affecting Florida also, and you are telling me you are going to reduce the research on this pest from \$3 million to half-a-million? Now, are we abandoning this program?

Dr. KING. Our commitment was to collect, to test, to culture and release potential biocontrol agents that would work on sweet potato whitefly.

Mr. PASTOR. How successful was that?

Dr. KING. To a certain extent we have done that.

Mr. PASTOR. Where?

Dr. KING. Mission, Texas, where part of that research was done. And we also then engaged in field trials where putting these natural enemies out and doing assessments on how well they do. We are at the point with some of these biocontrol agents that we think we can turn them over to private industry or to cooperators in the state for mass rearing and releases into the field. And that pretty much was our original mission.

I think there are still other biocontrol agents and there are other field studies and assessments that would be nice to have done, but I think we have done the work and have found some biocontrol agents that are helpful.

Mr. PASTOR. Let me ask. How effective was your work in Mission, Texas?

Dr. KING. I do not know the specifics on the field trials. I will be glad to try to supply those for you. I know in cotton, one of the things that have been done, and I am going to ask Dr. Schwalbe maybe to get into a little detail if that is okay.

Mr. PASTOR. Sure, that would be fine.

[The information follows:]

The APHIS Biological Control Laboratory in Mission, Texas, has supported the foreign exploration in search of exotic natural enemies for the sweet potato whitefly. In addition, it has supported the quarantine screening of the imported material, molecular identification technology, established cultures and developed mass rearing techniques in the laboratory and in the field. Three exotic parasitoids have effectively been mass produced in the field in screened cages and made available to researchers throughout the southern States. This technique of mass production can be applied to any state for increased local production and redistribution purposes. Tests have also resulted in exotic natural enemies transferring from agricultural crops to wild host plant refuges for conservation of natural enemies when targeted crops are plowed under. Greenhouse tests have resulted in significantly high parasitization of the whitefly on ornamental plants under controlled environmental conditions.

Dr. KING. The idea was using pesticides around fields and then just using biocontrol agents for the field, itself, which decreases the amount of pesticide use, but tends to delimit the natural enemies in specific areas.

Mr. PASTOR. One more question regarding the use of pesticides. We have found pesticides to be practically ineffective because the whitefly is highly mobile and virtually impossible to eradicate by direct application methods.

Dr. KING. I think these are special circumstances where there are not large populations. We can go in, say, in a cotton crop and actually do somewhat of a delimitation and then apply the natural enemies.

Mr. PASTOR. I can tell you because of what I have observed in Yuma and Western Maricopa County, that their numbers are so high that it is very difficult to know what fields are infested and which are free of pests. You can walk in downtown Phoenix, which has very little agricultural activity and, see whiteflies everywhere. So to tell me that you are going to apply pesticides around a field and that you plan to release this predator within this field is far from comforting or convincing. At least the little experience I have had during the last three years shows me you are going to have great difficulty solving the problem using this approach.

Dr. KING. That is not the total solution.

Mr. PASTOR. Okay.

Dr. KING. I hope I did not give you the wrong impression. In selected circumstances where the populations are low, this is one of the findings that we have found.

Mr. PASTOR. Chuck, welcome.

Dr. SCHWALBE. The Department's program against sweet potato whitefly was extremely complex. It was an arrangement of all the

Federal agencies working with the universities and so forth to develop a five-year strategy for its ultimate control.

Two years before the program was kicked off, APHIS saw the problem and we did some redirection of funds to go out and meet it, but we have been carrying a line item for sweet potato white fly for the last two years.

These last two years have really been quite successful in terms of the garnering together of natural enemies. And we have collected from all around the world over 20 different varieties of predators and parasites and they are in culture in our laboratories. All of these organisms have been released to field locations with cooperators from the northeast to the southwest. Numerous universities, state departments of agriculture, grower groups and so forth, but I think the highlight of this effort, at least from the biological control standpoint, and biocontrol is only one part of it, the highlight of this program was the last two years, the sort of coalition that formed between these government researchers and the industry. And last year in particular, some very important studies were done in California showing how these parasites can be integrated into a management program against the white fly by judiciously using pesticides around the edge of fields, thereby conserving these natural enemies in the middle. This coupled along with—and this was done in cotton. This coupled along with biological procedures for pink bollworm, in the same site, resulted in a very impressive reduction of pesticide applications for white fly from as many as 8 or 10 in control fields to on the average of 3 or 4 in these treatment fields and no pesticide was being used for pink bollworm. So it does really show how everybody chipping together can really make a difference against this pest.

Mr. PASTOR. Last year I asked the same question and I was encouraged because you were working with an insect from either Pakistan or Afghanistan that looked promising. This was a year ago, last year. And I said, "Well, how soon are we going to bring it over?"

And they said, "Well, we do not know what impact it will have in this country, so we are still testing it overseas. And we are not about to bring it here because we do not know what negative effects it may have."

Now you say that during in the last two years we have been conducting these tests. Yet, you also said you still were looking for predators which you will be hesitant to bring to this country for fear of the impact they would have here.

Still, I am glad to hear that for the last two years we have been doing this work, even though last year I heard that we had not done anything because we were concerned about these insects.

Dr. SCHWALBE. People approaching biological control come from different persuasions. And there are those that are anxious to find as many of these natural enemies overseas as possible and will continue to search and collect new agents, looking for better ones all the time in the short term. So there will always be more mountains to climb so to speak in terms of discovery. But in the short term crisis type of program like we have with whitefly, the time has to come where we say we have gone through an aggressive foreign exploration program, now we need to bring these back in,

evaluate them in the laboratory, find out how we can get them released into the fields and actually use them. And that is the position we are at at this point in the program. So I am not saying there are not more to be found in Afghanistan or Pakistan, but we are backing off from that part of the program.

WHITEFLY

Mr. PASTOR. What good news can I give my colleague from Florida—she is very concerned. Yesterday she sat here and said the tomato industry in Florida is going to be ruined if we do not do something about the whitefly. She was concerned about the reduction in research. What good news can I give her? Can I tell her that maybe next week we are going to be able to take these predators and insecticides/pesticides out in the fields of Florida so that we will not devastate that industry? And what can I tell my melon growers in Arizona?

Dr. SCHWALBE. There are no silver bullets—

Mr. PASTOR. Just tell me when, the date they will be able to either use a pesticide that is approved by EPA and that is going to be available to them so that their products are not ruined this summer or this year by whitefly. I have got to give them some hope.

Mr. PETERSON. Will the gentleman yield?

Mr. PASTOR. Certainly.

Mr. PETERSON. Do you agree that there is a problem with the tomato in Florida with white fly?

Dr. SCHWALBE. Absolutely. It is an enormous—but it is in all vegetable crops. What makes this such a vexing pest is the enormous host range. And that coupled along with its ability to transmit diseases, virus diseases in particular, from plant to plant makes it doubly problematic.

Mr. PASTOR. You have told me you are going to stop doing research, or are going to downscale it from \$3 million to half-a-million because now you have a strategy that may include herbicides, pesticides and predators.

Now my question to you is, how soon will the people in Texas and in Florida and Arizona and California be able to find a solution for this whitefly problem? Right now they do not have it. There is not a pesticide that is working. The whitefly moves in clouds. So what can I tell them? That now we are going to stop research because we have found several bullets, although not the “silver bullet”? How soon are they going to be able to buy a product or contract with a private entity to protect themselves?

Dr. SCHWALBE. It is important that the APHIS involvement in this sweet potato whitefly program is part of a larger picture. There are dollars being put in by other USDA agencies as well as States and to a very impressive degree the industry.

Mr. PASTOR. Now are you telling me that the \$2.5 million being cut from this program is going to be picked up by the private sector or universities or other entities? Is that your expectation or your hope?

Dr. SCHWALBE. To the extent that would be possible, that would be what we would try to encourage.

Mr. PASTOR. But what if it does not happen? Let us say it does not happen, a worst case scenario. So what do we do with the whitefly? What do we do?

Dr. KING. I do not think we have a good answer for you.

Mr. PASTOR. Okay.

Dr. KING. That is the answer, and it is not that we do not think that this is an important pest, and that it is not an important problem. We are involved in fire ants and bees coming up from Mexico, and in sweet potato whitefly. There are a whole litany of other problems that people would like us to work on, and that they consider equally as important in different parts of the country. It is a matter of putting that array out, looking at priorities and trying to pick the highest ones and the ones that we can do.

Mr. PASTOR. How do you develop that priority? Now here you have a pest devastating crops from Florida to California. So why is it not a priority? It is ruining the produce industry throughout the United States, from California to Florida.

Now, should it not be a priority? Or, what criteria do you use to established a priority?

Dr. KING. It depends on who you would talk to.

Mr. PASTOR. Okay, well, I am talking to you. [Laughter.]

Dr. KING. Other constituents would say that they think this money ought to go some place else.

Mr. PASTOR. Okay, let me ask you a question. Why did you decide that in this particular program you could downgrade it?

Dr. KING. This was a five-year program. We think it was accelerated in three years. We have some biocontrol agents that will work. We are ready to hand those off to people in the private sector and in the state that can increase the numbers very rapidly and release them into the field. We propose \$500,000 for that program to look at assessments and some other controls.

Mr. PASTOR. Well, let me ask you the question. How soon do you think the farmers will have some relief since you now have the insect protector and strategy to eradicate this pest? Now, how soon is that going to happen?

Dr. KING. We will have to look at the assessments when these populations are put in the field and find out. So I think the answer to that would be premature until we do these assessments.

Mr. PASTOR. Well, how long do you think these assessments will take?

Dr. KING. I do not know. Some of them are in progress now. We certainly have money for six months of this year left, and we will certainly focus on trying to get that information for you and the people of concern.

Mr. PASTOR. Good. Hopefully it will be within a short period of time because people are losing their crops right now, and as soon as you can provide it, it will be greatly appreciated.

Thank you, Mr. Chairman.

Mr. DURBIN. Thank you very much, Mr. Pastor.

Mr. Thornton.

BIOCONTROL

Mr. THORNTON. Mr. Chairman, I would like to follow up briefly because you are raising a point that is most serious, and that is

the problem of technology transfer. The problem is how do you get research and discoveries from the laboratory into commercial use. This is a very serious problem in this instance where, as my colleague has pointed out, there is an overwhelming need for relief right now.

What is your experience with industry in terms of their willingness to pick up these new predators and to make the investment that they must make in order to increase the population and distribute and sell them?

Dr. KING. Our work with private industry in the bio-tech sector have been quite good. I think those companies are pretty well capitalized and better so than the biocontrol industry.

Mr. THORNTON. Better so?

Dr. KING. Yes, sir.

Mr. THORNTON. So bio-tech is better than biocontrol.

Are we dealing with biocontrol here?

Dr. KING. We are dealing with biocontrol. There are a lot of relatively small companies that are just getting started, that are in the business of rearing natural enemies for crops. But the people that I have talked to have been fairly small, not heavily capitalized, but willing not to take great risks until we get some good information.

Mr. THORNTON. Are there proprietary interests that they can protect? What keeps their company from making an investment and proving it successful, and then having a larger company come in and wipe them out?

Dr. KING. I do not know the answer to that.

Dr. SCHWALBE. In the area of biological control, this is really not an issue. Probably one of the larger impediments to seeing this technology commercialized—

Mr. THORNTON. Yes?

Dr. SCHWALBE. Has to do with the unpredictability of the market. And while there are programs in place for fly control and, you know, feeding yards and things of that sort and, of course, selling the lady beetles, the diversity of problems that can be dealt with through biocontrol on a predictable basis really is not there.

We just concluded a meeting with the Association of Natural Biological Control Producers, trying to understand their interests and how our investments and interests in biological control can be harmonized better with theirs. And that seems to be part of the problem.

Mr. THORNTON. Harnessing our inventive genius to the marketplace is a constant problem, and it looks to me as though we have a clear example of that right here, where you have a predator that should work, but how do you get somebody to take the risk of breeding it and disseminating it, and what if it does not work, and how do you get the marketplace to agree to purchase this product.

Is there anything that you can be doing to cut through barriers for the dissemination of knowledge into the marketplace?

Dr. KING. I think we just want to make sure that we can facilitate and help these small companies as best we can; that we do not have undue delays when they want to transfer predators from state to state, which they do; and that we can go through the process

and not have any undue delays if indeed they are trying to get a product out for production.

Mr. THORNTON. Thank you.

And thank you for yielding.

Mr. DURBIN. Thanks, Mr. Thornton, and I appreciate this panel's testimony today. Mrs. Vucanovich has a few questions she would like answered for the record. We have had a good, lively exchange as they say in the business. And we will be taking a look at the budget request in more detail.

ANIMAL DAMAGE CONTROL ENVIRONMENTAL IMPACT STATEMENT

Ms. VUCANOVICH. I am very interested in the Animal Damage Control Program. As you know, in areas out West, like Nevada, an efficient and effective ADC program provides farmers and ranchers with peace of mind about their livestock.

It is my understanding that a national Environmental Impact Statement on the Animal Damage program was to be completed. Is this finished and has the document been released and when will a "Record of Decision" be published?

Response. The Final Environmental Impact Statement [EIS] for the Animal Damage Control—ADC—program was completed in March 1994, and is now being reviewed in the Department. The notice of availability will appear in the FEDERAL REGISTER after this review. Following the required 30-day time period after the notice has been published in the FEDERAL REGISTER, the Record of Decision will signed.

Ms. VUCANOVICH. What additional steps are necessary to fully implement the EIS in ADC program operations?

Response. ADC employees will need to be trained in the National Environmental Policy Act—NEPA—requirements, for example, monitoring, evaluation, and implementation; and local or site specific environmental assessments will be required.

Ms. VUCANOVICH. Will there be additional cost to fully implement the EIS in the ADC program? If so, how much and what will these costs cover?

Response. Yes. The Bureau of Land Management—BLM—has estimated that they spend approximately \$1 million annually on ADC activities in the Western United States to minimally comply with NEPA.

Ms. VUCANOVICH. The FY 95 budget request for the ADC program reflects a significant reduction for operational program activities. Was this reduction evaluated in the EIS?

Response. No, the EIS did not look at funding reductions or the different funding levels of the program. The EIS evaluated the impacts resulting from ADC's programmatic activities between the years 1988 through 1992.

IMPACTS OF PROPOSED BUDGET REDUCTION

Ms. VUCANOVICH. What impacts will the proposed budget for FY 95 have on ADC operations and research?

Response. APHIS will reduce programs involving direct control and will not pursue new cost-sharing initiatives. The Agency will rely on States and private entities to assume greater responsibility for activities involving direct control of damage by predators such as beavers, coyotes, and other species which damage the agricultural community.

Ms. VUCANOVICH. Can APHIS provide an estimate of the financial burden that the proposed budget reduction will place on various agricultural industries? For the record if they cannot give the information presently.

Response. If cooperators provide additional funding to offset the proposed reduction, they will incur an additional financial burden of \$2.66 million. Most of the cost would be absorbed by the sheep and livestock industries.

DENVER WILDLIFE RESEARCH CENTER RELOCATION

Ms. VUCANOVICH. In your testimony you mentioned the Denver Wildlife Research Center. Please provide more information on the Agency's plans (and timeline) to relocate this center. Will the function and goals of the center remain after it is relocated? How does the budget proposal reflect these plans?

Response. To date, a total of \$10.5 million has been appropriated for this project, as follows: \$6.0 million in FY 1990, for design and construction of the animal research laboratory (Phase 1A); \$2.5 million in FY 1992, for design and partial con-

struction of animal holding facilities (a portion of Phase 1B); and \$2.0 million in FY 1994, for remainder of construction costs of animal holding facilities.

Construction of Phase 1A began in September 1993. Completion is expected by about December 1994. Because the low bid was significantly higher than anticipated, the initial \$6.0 million earmarked for Phase 1A was insufficient to complete this phase of the project. A decision was made to temporarily avert the shortfall by shifting into Phase 1A funds appropriated in FY 1992 for Phase 1B. The additional \$2.0 million provided in FY 1994 restored sufficient funds for completion of Phase 1A.

Phase 1B.—The design contract for Phase 1B was awarded in October 1993. The design work is approximately 25 percent complete as of April 1994. Construction is targeted to begin in November 1994, on approximately one-third of this phase. Additional funding will be required to complete the remaining two-thirds of Phase 1B.

Phase 1C.—A breakout of costs associated with Phase 1C follows:

Bulk chemical storage—\$25,000.

Two-Story Research Facility—\$5,193,750.

Animal Research Building Support Wing—\$1,450,050.

Pyrotech Storage—\$20,000.

No funding is presently available for action on Phase 1C.

Phase II.—According to the master plan, costs associated with Phase II are as follows:

Administration Building—\$1,537,500.

Two-Story Research Building—\$4,500,000.

Technology Transfer Center—\$1,512,000.

Conference Center—\$688,500.

Main Entry Lobby—\$240,000.

No funding is presently available for action on Phase II.

Phase III.—At the present time, sufficient demand for Phase III (Exotic Species Research Building and Research Building #3) is not present nor is it expected to be for the foreseeable future.

The goal of the center will remain the same following the relocation to Fort Collins, which is to provide the Animal Damage Control operational program and the States and industry with the needed control tools, with emphasis on nonlethal methods, to help resolve problems that occur when species of wildlife cause damage to agricultural, urban, or natural resources or present a threat to public health or safety.

The new building will: Provide modern, state-of-the-art laboratory facilities to meet the research needs of the current ADC operational program; allow for increased cooperation and information sharing between university scientists and DWRC scientists; and provide outdoor animal holding pens which are no longer viable at the current DWRC complex due to urban development.

Additional funds for this project, as detailed in the Master Plan, are not included in this year's budget request.

AQUACULTURE

Ms. VUCANOVICH. The proposed budget includes a significant amount for aquaculture. Is this a shift of emphasis and funding away from livestock production?

Response. No, the proposal is not a shift away from livestock production. Rather, it is a broadening of APHIS' focus to provide support to this important industry which is currently the fastest growing segment of American agriculture. We do not see this as a weakening of our commitment to protect America's animal health resources.

ADC ACTIVITIES ON PUBLIC LANDS

Ms. VUCANOVICH. It is my understanding that there have been a number of areas on public lands where ADC operations have recently been delayed, suspended or significantly restricted. What is the cause of these difficulties?

Response. One of the causes for the delay and suspension of ADC activities on public lands was BLM's problems in completing the necessary NEPA documents. Another cause of delays and/or suspension of predator control activities was the filing of numerous appeals or lawsuits challenging the environmental documentation prepaid.

Ms. VUCANOVICH. What is being done to resolve these problems?

Response. APHIS is currently working with the BLM to improve lines of communication between the agencies and revise their Memorandum of Understanding to address the issues of who will have responsibility for NEPA compliance.

Ms. VUCANOVICH. Can APHIS provide an estimate of the additional losses, if any, which have resulted from these program interruptions?

Response. We do not have figures available on the value of livestock that would have been saved if the ADC control activities had not been interrupted.

Ms. VUCANOVICH. Are there any questions about ADC's authority and responsibility to work on the public lands?

Response. APHIS has the authority to conduct activities on public lands. However, through established cooperative relationships with each BLM District and implementation of APHIS policy, ADC conducts activities only upon request. There have been questions raised in the past regarding who is responsible for the NEPA and the environmental decision-making process on some public lands. The issue has been resolved with the U.S. Forest Service, and ADC is currently working with the BLM to resolve it with them as well.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Statement of Dr. Lonnie J. King, Acting Administrator, Animal and Plant Health Inspection Service, before the House Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies.

Mr. Chairman and members of the Committee, I appreciate the opportunity to report on our continuing efforts to protect American agriculture and its ability to affordably and safely feed Americans and others, and its contribution as part of the largest industry in our economy. I would like to report briefly on our Agency's mission, organization, current activities, and the issues we face.

First, let me introduce some members of our management team with me today. They are Deputy Administrators, Mr. Bobby R. Acord for Animal Damage Control; Dr. Dale F. Schwindaman for Regulatory Enforcement and Animal Care; Dr. Alex B. Thiermann for International Services; Dr. Charles P. Schwalbe, Acting Deputy Administrator for Plant Protection and Quarantine; Mr. John H. Payne, Acting Director of Biotechnology, Biologics, and Environmental Protection; Dr. Donald W. Luchsinger, Acting Deputy Administrator for Veterinary Services; and Mr. Kevin Shea, Director of the Budget and Accounting Division.

AGENCY MISSION

The mission of the Animal and Plant Health Inspection Service (APHIS) is to protect American agriculture by providing leadership in ensuring the health and care of animals and plants, and thus improving agricultural productivity and competitiveness. This primary objective helps to keep food safe, plentiful, and inexpensive. Our programs help keep our agricultural industry efficient, economically sound and successful, thereby contributing to our national economy and the public health. APHIS accomplishes this mission by: excluding exotic agricultural pests and diseases; detecting and monitoring incursions of agricultural pests and diseases; managing endemic agricultural pests, diseases, and predators; providing scientific and technical services; assuring the purity, safety, effectiveness, and potency of veterinary biologics products; regulating release of veterinary biologics; and regulating certain plants, and other organisms developed through biotechnology; facilitating agricultural exports; protecting the welfare of animals; protecting endangered species; ensuring that our activities safeguard the environment; and collecting, analyzing, and disseminating information.

AGENCY ORGANIZATION

APHIS was established as the Animal and Plant Health Service in 1971. The name was changed to Animal and Plant Health Inspection Service when other functions were added the following year. The Agency headquarters are located in Washington, D.C., and Hyattsville, Maryland. Veterinarians, inspectors, plant pathologists, entomologists, wildlife biologists, and other scientists and experts are located throughout the United States, and in several foreign countries. Six program delivery units, each representing unique scientific and regulatory disciplines, carry out the Agency's mission.

Veterinary Services employs veterinarians, animal health technicians, epidemiologists, and other animal health professionals. It conducts programs to ensure and protect the health of the Nation's livestock and poultry resources; prevents the entry of dangerous animal diseases; enhances the export of livestock and poultry; cooperates in disease control and eradication programs; and conducts national animal health monitoring and surveillance activities.

Plant Protection and Quarantine employs entomologists, plant pathologists, and others with various scientific backgrounds. It conducts programs to protect the Nation's agricultural resources from the entry of plant pests and animal diseases; cooperates in

plant pest survey, control, and eradication; and certifies U.S. agricultural products for export.

Animal Damage Control provides Federal leadership in managing problems caused by wildlife. The program employs wildlife management specialists whose responsibilities are to protect America's agricultural, industrial, and natural resources and to safeguard public health and safety, while considering a wide range of legitimate public interests which may conflict with one another. These interests include wildlife conservation, biological diversity, and the welfare of animals as well as the use of wildlife for purposes of enjoyment, recreation, and livelihood.

Biotechnology, Biologics, and Environmental Protection employs scientists with training in multiple disciplines such as chemistry, molecular biology, ecology, veterinary medicine, law, microbiology, and genetics. This unit coordinates the development and execution of biotechnology regulatory policy within APHIS and other USDA regulatory agencies; assures the purity, safety, potency, and efficacy of veterinary biological products intended for the diagnosis, prevention, and treatment of animal diseases; analyzes the environmental impact of all APHIS programs; and, where necessary, prepares environmental assessments or impact statements to ensure compliance with all applicable environmental laws and regulations. This program is

also responsible for securing and maintaining pesticide registrations for agency programs. We also conduct pesticide residue analyses on fruits and vegetables for food safety purposes for the Agricultural Marketing Service and conduct environmental monitoring as part of APHIS' "Circle of Environmental Protection" program.

International Services conducts activities outside the United States which support the primary goals of protecting our nation's agriculture and enhancing U.S. agricultural exports by establishing an information network on the world animal and plant pest and disease situation; negotiating with foreign officials concerning entry requirements for this country's agricultural products; cooperatively conducting agricultural pest and disease prevention, control, and eradication programs in foreign locations; and conducting preclearance programs of agricultural products destined for the United States.

Regulatory Enforcement and Animal Care employs veterinarians and other specially trained personnel to direct and coordinate investigations of alleged violations of law or Departmental rules and regulations, and conducts animal welfare inspections to ensure the proper stewardship of animals, whether they are destined for research, exhibition, or other regulated industries.

APHIS, through innovative and aggressive recruitment, has been able to attract the best qualified and most representative work force possible. APHIS is constantly designing initiatives to strengthen the overall diversity of its workforce. Among the more visible and innovative initiatives are the Agency Scholarship programs and Centers of Excellence. The Saul Wilson Scholarship supports four minority and women students in their pursuit of a veterinary medicine degree and the Regulatory Enforcement and Animal Care Scholarship supports a Native American high school student pursuing a college degree. APHIS aggressively pursued the creation of Center of Excellence on three 1890 campuses to advance agency work and promote stronger partnerships with these institutions. APHIS is ranked among the top USDA agencies for Hispanic representation in its workforce, almost twice the civilian workforce representation. A highly skilled work force and a working environment that stimulates and challenges our people are key to maintaining internationally recognized laboratories and support systems that provide technology, research, scientific information, and technical support services for APHIS programs, agricultural producers, and the public.

APHIS employs 5,157 permanent full-time people and 1,654 others in carrying out field activities on a national basis through 10 regional offices and 440 field offices, including area offices, work stations, technical centers, and animal import centers. We

cooperate with State and local agencies, private groups, and foreign governments. APHIS performs work in the 50 States, Guam, Puerto Rico, Virgin Islands, Mexico, Central America, South America, the Caribbean, Western Europe, Australia, Asia, and Africa.

CURRENT ACTIVITIES AND ISSUES

To achieve our mission, all of our activities must be channelled toward maintaining the favorable health status of our national food animal populations and plant commodities. This objective means that our programs reduce, and in many cases, eliminate plant pests and animal diseases. This objective is key to making American agricultural products viable -- economical for producers, safe and affordable for food consumers, and competitive for international trade and commerce. Accomplishing our mission begins by knowing and understanding the customers we serve.

Initiatives

We must be sensitive and responsive to customers in the broadest sense -- not just traditional agricultural commodity groups, but others who are directly or indirectly affected by our services. Because of the general public's concern about food safety, we propose a pre-harvest pathogen reduction program. The goal of

this program is to provide the consumer with a safe, reliable, and affordable animal food product supply by reducing biological and chemical pathogens at the farm level. The pre-harvest program will initially focus on risk assessment techniques, Hazard Analysis and Critical Control Point systems (a method of focusing on areas where changes will have a positive effect), data collection and analysis, identification and traceback, and monitoring and surveillance. This proactive approach to increase the overall awareness of food safety from the farm to the table will lead to increased consumer confidence in the safety of the country's food supply.

Public concern has recently surfaced over bird-induced impacts on the burgeoning aquaculture industry. Aquaculture is currently the most rapidly growing segment of agriculture. Our efforts would help reduce bird damage to aquaculture while ensuring the continued viability of migratory birds.

International travelers are our customers as well. In FY 1993, 47 million passengers arrived at U.S. ports, an increase of almost 7 million over FY 1992. Passenger arrivals are projected to steadily increase, with two new terminals in Atlanta and Denver opening in FY 1995. To respond to the projected increased demand for inspection services including aircraft, vessels, and rail cars, user fee generated funding needs to be available for increased staffing and equipment such as x-ray machines. These

activities help protect the multi-billion dollar agriculture industry customers and provides the least burdensome services possible to international traveling customers.

Considering our customers in the broadest sense, we are aware of the public's deeply held concern with issues such as animal welfare, wildlife values, and environmental protection and the consequences and tradeoffs of scientific risk-management decisions.

Under the Animal Welfare Act, APHIS carries out activities designed to ensure the humane care and handling of animals used in research, exhibition, or the wholesale pet trade. We place primary emphasis on inspection of facilities, investigation of complaints, reinspection of problem facilities, and training of inspectors. APHIS continued its efforts to increase the quality of inspections in FY 1993. The program implemented a comprehensive computerized inspection tracking system known as the Licensing Application Registration Information System throughout the nation. This system increases program efficiency by providing an on-line database on licensees and registrants as well as the capability for establishing a risk-based inspection ranking system.

The Animal Damage Control program protects American agriculture from detrimental predators and other animals causing losses to

agriculture, and risks to public health and safety through identification, demonstration, and application of the most appropriate methods of control. For example, APHIS continues to work with the Texas Department of Health to seek solutions to the problem of canine rabies which has spread to several counties in south Texas. This particular strain of rabies originated in Mexico among feral dogs, and has spread during the past 3 years into south Texas, where both coyotes and feral dogs are now transmitting the disease. ADC is working with State and County officials to reduce coyote populations in and around densely populated areas where rabies has been found.

APHIS uses environmental and scientific staff, and the National Monitoring and Residue Analysis Laboratory (NMRAL) at Gulfport, Mississippi to carry out a "circle of environmental protection" concept that enables APHIS' operational programs to comply in a proactive fashion with all environmental requirements -- the National Environmental Policy Act and other applicable statutes, executive orders, and regulations. Environmental scientists work with program planners to identify and develop viable alternatives to current control and eradication programs and to document APHIS' environmental planning activities. The NMRAL provides analytical chemical services in support of APHIS' cooperative treatment programs employing agrochemicals to control or eradicate plant and animal pests. Principal programs supported include agricultural quarantine inspection, grasshopper, imported

fire ant, boll weevil, Mediterranean fruit fly, and gypsy moth. In addition, the laboratory's testing of various food products for pesticide residues is important to the Department's efforts to promote food safety. The program develops monitoring plans that are used to assess the impact of Agency actions on the environment, and analyzes samples of soil, water, and crops for pesticide residue to determine the safety of ongoing and alternative programs.

Our traditional agricultural trading boundaries have expanded considerably and so have our activities. We must maintain and enhance our position as a world leader in ensuring animal and plant health. We continually anticipate and adjust for changes in the world that affect our ability to carry out the APHIS mission. A mission that has traditionally focused on preventing the entry of exotic pests and diseases must accommodate an increasingly important role in facilitating U.S. agricultural exports.

The import/export program protects domestic livestock, poultry, and wildlife from diseases, including those transmissible from animals to humans. For example, we propose that certain cattle imported into the United States from Mexico be sent to quarantined pastures or feedlots or to quarantined holding facilities and have a 60-day post entry tuberculin test. This action would help prevent potentially infected steers and spayed

heifers from Mexico from spreading tuberculosis to U.S. cattle. APHIS promotes markets abroad by negotiating with several countries to establish or update animal health protocols for the expansion of U.S. origin animals, semen, and embryos. APHIS continued to discuss with Mexico and Canada, changes in import health requirements related to NAFTA. These activities are vital to the protection and expansion of the \$6 billion U.S. animal and germ plasm export market.

Similarly, the objective of international programs is to protect U.S. agriculture and to promote the export of U.S. agricultural products by actively addressing pest and disease problems at their origin rather than waiting for them to arrive at our ports of entry and borders. APHIS maintains a presence in countries that are significant agricultural trading partners and these may be potential sources of economically dangerous agricultural pests and diseases. APHIS conducted preclearance inspection of fruits and vegetables in 21 countries worldwide. APHIS personnel at overseas locations provide an effective first line of defense against the entry of foreign plant and animal diseases and pests into our country. Their presence also facilitates the export of U.S. agricultural products, and promotes the exchange of science and technology in animal and plant health by ensuring that regulatory decisions, import requirements, and export certifications are based on sound biological principles and data, and are not an inappropriate barrier to trade.

The pest detection program provides improved information on plant pests and diseases, to support the competitive position of U.S agricultural products in global markets. This includes effective surveys to provide early detection of exotic pests soon after their introduction to a new geographic range to allow early eradication, negotiation of the most favorable positions in our trade agreements, and the collection of accurate and timely biological information which supports efficient use of pest management resources. The General Agreement on Tariffs and Trade negotiations and the North American Free Trade Agreement may lead to reductions in tariffs or other traditional economic barriers and subsequently raise the importance of phytosanitary considerations in international trade agreements.

Mediterranean fruit fly infestations in California continue to threaten a \$1.6 billion fruit and vegetable domestic and export industry. Last year, an international team of fruit fly scientists recommended a shift in eradication strategy from local containment of individual outbreaks, to an area-wide approach. The team suggested the release of sterile Medflies and enforcement of regulations throughout the entire Los Angeles Basin for 2 years. APHIS, in cooperation with the California Department of Food and Agriculture, agrees with this approach, which would increase the likelihood of successful eradication and would provide immediate protection for California's domestic and export agricultural markets.

Applying the latest scientific approaches and technologies to all aspects of our work allows us to become more productive and effective. APHIS brings together Federal and State agencies, industries/businesses, academe, and associations which can play important roles in helping accomplish the APHIS mission. In the animal health monitoring and surveillance program, APHIS works cooperatively with other entities to maintain the capability for consistent disease surveillance and detection, emergency disease preparedness and response, animal health monitoring, and epidemiological delivery. These activities enable APHIS to rapidly eliminate foreign animal disease outbreaks to assess the risk of new and emerging domestic animal health issues, to support APHIS control and eradication programs and to enhance the quality, safety, and competitiveness of U.S. food animal products. Last year, APHIS conducted approximately 300 investigations for suspected foreign animal disease and began two projects to analyze and disseminate information on E. coli 0157: H 7, the foodborne pathogen responsible for serious human illness and death in Western States.

The biotechnology program regulates the field release, interstate movement, and importation of genetically modified organisms. The intent is to certify and ensure that the introduction and field testing of new products do not present potential risks to America's plant and animal resources, industries, the general public, or the environment. APHIS experienced significant

growth in workload, with an increasing volume of transgenic plants being tested in the field and coming to the market place. Since 1987, the number of release permits for field tests of transgenic plants has increased from 5 to 141 in FY 1993. The program fosters technology transfer by allowing for the safe field testing of potentially beneficial plants and micro-organisms. The program enhances technology transfer by working to reduce domestic and international barriers to biotechnology development and trade. Both activities support the President's goal of maintaining America's competitive edge in biotechnology; an industry potentially worth over \$50 billion by 2000, with agricultural biotechnology being the largest part.

The ADC methods development program protects American agriculture and other resources through development of scientific information, identification, and demonstration of the best methods for controlling wild and free ranging animals that are detrimental to agriculture, other wildlife, and the public safety. In support of this mission, research and development of control techniques and devices for the operational program and APHIS clientele are provided by the Denver Wildlife Research Center (DWRC). DWRC made progress in research to identify an immunocontraceptive for use on deer and other mammals as a method to resolve site specific wildlife problems. Among other projects, DWRC began an effort with the U.S. Forest Service to

evaluate the efficacy of three sulfur based repellents to protect seedlings from deer browsing and a study of the brown tree snake in Guam with the U.S. Fish and Wildlife Service. Approximately 55 percent of the methods development effort was devoted to developing alternative, nonlethal methods. In FY 1993, construction began on a new ADC methods development facility at Fort Collins, Colorado. This is the first phase of a three-phase project to relocate the center from the current Denver site.

Making the most of limited resources is a challenge we all face and requires innovation and old-fashioned belt tightening. This means delivering the highest quality services at the lowest possible cost. We must pursue better integration of functions and greater resource sharing; more facilitation and less controlling and promulgation of rules and regulations; and designing of innovative processes and programs that provide flexibility. As part of this effort, APHIS proposes to adjust its budget to reflect plant health functions performed. Currently, programs represent a specific plant pest, a pest prevention or control program, or technical support. The functional budget approach would provide for consistent pest exclusion, survey and monitoring, and scientific and technical services without direct ties to traditional plant pest control programs. The structure would allow for continued survey and

monitoring after pest eradication activities are completed. This budget adjustment is similar to the restructure of animal health activities that became effective in FY 1994. It would also allow flexibility in responding to changing pest and disease situations.

APHIS has selected eight work sites for "reinvention laboratories." A reinvention lab is an opportunity to put the philosophy of reinventing government into practice. This means empowering people by giving them more responsibility to better serve customers and create a culture change in the work environment. While each work group will approach its experiment from a holistic perspective, each will focus on one aspect of "changing the way in which its members do business." This focus will allow for measuring the type and rate of change which may occur over a six month to two year period. The knowledge gained from these laboratories can then be applied to other APHIS operations. APHIS has reinvention laboratories regarding Simplifying Rulemaking, Expanding Options for User Fee Collections, and Enhancing Service Delivery Through Decentralization.

APHIS plans to consolidate three unit Northeast regional offices, which is projected to save an estimated \$3.2 million in operating costs over 15 years and reduce administrative positions required

to support field programs. Consolidation of other regional offices will follow as practicable.

Given the budget situation, we must recognize that some programs need to be reduced or eliminated. For example, no control substance that is registered for use on most agricultural lands has proven effective against the imported fire ant. Since 1985, the Agency has not received any requests from States for cooperative treatment programs, and many States have proven themselves able to successfully eradicate small isolated infestations outside regulated areas. Consequently, we propose to discontinue specific line item funding but would continue to evaluate the efficacy of regulatory treatments for preventing the further artificial spread of the pest.

FY 1995 BUDGET REQUEST

The request proposes \$436.4 million for salaries and expenses, a decrease of \$3.2 million from the FY 1994 current estimate of \$439.6 million. Of the proposed amount, \$101.9 million would be derived from AQI user fees, an increase of \$10.4 million over the FY 1994 level because of increased international traffic. APHIS proposes that fees collected in the AQI user fee account remain available without appropriation action to better provide services that are driven by demand. The budget requests \$7 million for buildings and facilities to fund repairs, alterations, and

renovations at existing facilities and structures, the same as the 1994 current estimate.

Among several program funding shifts, the budget proposes \$5.7 million for a pre-harvest pathogen reduction program to initiate efforts to promote food safety and \$0.5 million for an aquaculture program to reduce bird damage. The budget proposes funding of \$23.4 million for the ADC program, a decrease of \$2.7 million below the 1994 current estimate. APHIS will reduce current programs involving direct control and rely on States and private entities to assume greater responsibility for such activities.

APHIS proposes a consolidated plant pest survey line item which would combine survey activities of several plant program line items. This streamlined program would provide early detection of exotic plant pests to prevent sustained infestations and will monitor the effectiveness of plant pest management programs. The budget requests \$13.1 million, a decrease of \$3.6 million from the 1994 current estimate. Also proposed is the consolidated plant pest management line item which would include regulatory and control activities of several plant program line items. The budget requests \$17.2 million, a decrease of \$1 million from the 1994 current estimate. The decreases in these survey and control programs reflect administrative efficiency savings resulting from the Secretary's plan to streamline the Department and the

elimination of the sweet potato whitefly, imported fire ant, and honey bee pests line items. The limited monitoring and technical assistance provided in support of the eliminated programs will be funded from the new plant program methods development line item.

APHIS proposes \$59.4 million for animal health monitoring and surveillance which is a decrease of \$0.5 million from the 1994 current estimate. This decrease reflects administrative efficiency savings and staff reductions from the Secretary's plan to streamline the Department.

CONCLUSION

Since its inception, APHIS has played a crucial role in protecting American agriculture. In this role, we will continue to face many challenges relating to plant and animal pest and disease conditions, increases in agricultural production and trade, and rising public concerns about food safety, environmental quality, and the humane treatment of animals. Because of changes in production, marketing, and public expectations, changes are needed in prevention, control, and eradication strategies. There is a shifting emphasis from animal and plant pest and disease control to animal and plant health, and a corresponding new emphasis on monitoring and surveillance to ensure the health and safety of agricultural products.

We appreciate the Committee's strong support of our programs in the past, and look forward to meeting the challenge of protecting and strengthening American agriculture in the future. We will be happy to answer any questions.

BIOGRAPHICAL SKETCH

GEORGE O. WINEGAR

Dr. George O. Winegar is the Assistant Deputy Administrator for Veterinary Services (VS), Animal and Plant Health Inspection Services (APHIS). He has served in that position since June 4, 1990. He was born in Fowlerville, Michigan, on August 30, 1934. Dr. Winegar earned his Doctor of Veterinary Medicine Degree at Michigan State University (MSU) in 1962.

After earning his veterinary degree, Dr. Winegar began his career with the Agricultural Research Service as a field veterinarian in Southeastern Michigan and served in that capacity for 5 years. From 1967-1973, he was assigned to a tuberculosis research project at MSU where he earned a Master's degree. From 1973-1975, he was the USDA representative for disease control programs in Nicaragua, Honduras, and El Salvador with special emphasis on preventing the entry of exotic diseases. From 1975-1982, he was reassigned to the Michigan area office but participated in several projects in Latin America sponsored by USDA and the Foreign Agricultural Organization. During this period, he also completed the Veterinary Administrative Development Program.

In June of 1983, Dr. Winegar moved to Hyattsville, MD to become the Senior Staff Veterinarian for export animal activities on the Import/Export Animals Staff and was involved in negotiation of health protocols with foreign governments to permit the export of U.S. livestock. During this period, Dr. Winegar completed the Senior Executive Service training program. In June of 1990, Dr. Winegar was appointed as the Assistant Deputy Administrator of Veterinary Services.

Dr. Winegar resides in Laurel, Maryland, with his wife Lois. They have 4 grown children and 4 grandchildren.

BIOGRAPHICAL SKETCH

MARSHALL F. KIRBY

Mr. Marshall F. Kirby is Associate Deputy Administrator, International Services (IS), Animal and Plant Health Inspection Service (APHIS). He was born in Makate, Phillipines, and earned a Bachelor of Science Degree from the University of San Francisco in 1969; a Master of Science Degree from the University of Florida in 1972; and an Associate of Arts in Management Degree from the University of Maryland-College Park in 1983. Mr. Kirby also served in the Peace Corps as a volunteer nematologist in Suva, Fiji, from 1976-1978.

Mr. Kirby joined APHIS as a Plant Pathologist in Westhampton Beach, New York, in 1979. In 1989, he was transferred to Agana, Guam, where he served as an Agriculturalist. He was transferred in 1984 to Canberra, Australia to serve as a Plant Protection and Quarantine (PPQ) officer. In 1986, he became Chief Operations Officer for PPQ in Hyattsville, Maryland. He transferred in 1988 to Guatemala City, Guatemala to serve as PPQ's Area Director for Central America and Panama. In 1992, he moved back to Hyattsville, Maryland, in the capacity of Regional Director for the Asian Pacific Region for PPQ. In 1993, he was named Associate Deputy Administrator for IS.

As Associate Deputy Administrator, Mr. Kirby assists the Deputy Administrator in the management of all major animal and plant health programs overseas such as screwworm, foot-and-mouth disease, and other exotic disease eradication, control, and monitoring programs.

Mr. Kirby resides in the Washington, D.C. metropolitan area with his wife, Noreen, and their two children.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Purpose Statement

The Animal and Plant Health Inspection Service (APHIS) was established by the Secretary of Agriculture on April 2, 1972, under the authority of Reorganization Plan No. 2 of 1953 and other authorities. The primary mission of APHIS is to protect the Nation's animal and plant resources from diseases and pests in order to preserve the marketability of U.S. agricultural products within this country and for export. The mission is carried out under the major areas of activity, as follows:

Pest and Disease Exclusion: The Agency conducts inspection and quarantine activities at U.S. ports-of-entry to prevent the introduction of exotic animal and plant diseases and pests. The Agency also participates in inspection, survey, and control activities in foreign countries to reinforce its domestic activities. User fees cover phytosanitary certificates and inspection services for international passengers, and commercial vessels, aircraft, trucks, and railroad cars.

Plant and Animal Health Monitoring: The Agency conducts programs to assess animal and plant health, detect endemic and exotic diseases and pests, and ensure compliance with interstate movement and other disease control regulations within the jurisdiction of the Agency.

Pest and Disease Management Programs: The Agency carries out programs to control and eradicate plant pest infestations and animal diseases that threaten the United States; reduce agricultural losses caused by predatory animals, birds, and rodents; provide technical assistance to cooperators such as States, counties, and farmer or rancher groups, and foundations.

Animal Care: The Agency conducts regulatory activities which ensure the humane care and treatment of animals and horses as required by the Animal Welfare and Horse Protection Acts. These activities include inspection of certain establishments which handle animals intended for research, exhibition, and as pets, and monitoring of certain horse shows.

Scientific and Technical Services: The Agency performs other regulatory activities, including the development of standards for the licensing and testing of veterinary biologicals to ensure their safety and effectiveness; diagnostic activities in support of the control and eradication programs in other functional components; applied research aimed at reducing economic damage from vertebrate animals; development of new pest and animal damage control methods and tools; and regulatory oversight of genetically engineered products.

There were 5,157 permanent full-time employees and 1,654 other than permanent full-time employees as of September 30, 1993. Of the total, 951 permanent full-time employees and 74 other than permanent full-time employees work in the Washington D.C. metropolitan area. Field activities are managed on a national basis through 10 regional offices and 440 field offices, including area offices, work stations, technical centers, and animal import centers. Much of the work is conducted in cooperation with State and local agencies, private groups, and foreign governments. APHIS performs work in the 50 States, Guam, Puerto Rico, Virgin Islands, Mexico, Central America, South America, the Caribbean, Western Europe, Australia, Asia, and Africa.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Available Funds and Staff-Years1993 Actual and Estimated, 1994 and 1995

Item	1993 Actual		1994 Estimated		1995 Estimated	
	Amount	Staff-Years	Amount	Staff-Years	Amount	Staff-Years
<u>Appropriated:</u>						
Salaries and Expenses.....	\$349,538,000	4,324	\$348,104,000	4,343	\$334,539,000	4,137
Transfer to Office of the Secretary.....	-212,000	-	-	-	-	-
Agricultural quarantine inspection user fees.....	83,362,000	1,530	91,460,000	1,604	101,860,000	1,823
Emergency transfers (CCC)	16,094,404	115	-	-	-	-
Puerto Rico cattle tick.....	10,825,000	-	12,472,000	-	-	-
Buildings and Facilities.....	10,400,000	-	10,145,000	-	6,973,000	-
	470,007,404	5,969	462,181,000	5,947	443,372,000	5,960
<u>Obligations under other USDA Appropriations:</u>						
Agricultural Cooperative Service: for administrative support.....	145,549	3	147,000	3	-	-
Agricultural Marketing Service: for administrative and technical support.....	1,750,000	27	1,750,000	27	1,750,000	27
Agricultural Research Service: for administrative support.....	7,000	-	7,000	-	7,000	-
for plant control.....	131,262	-	135,000	-	135,000	-
for animal control.....	27,109	-	30,000	-	30,000	-
for systems furniture.....	41,000	-	-	-	-	-
Agricultural Stabilization and Conservation Service: for testing of tobacco samples.....	150,000	-	150,000	-	150,000	-
Cooperative State Research Service: for a biotechnology consultant.....	35,000	1	-	-	-	-
Federal Grain Inspection Service: for administrative support.....	965,300	31	965,000	31	965,000	31
Food Safety Inspection Service: for administrative support.....	30,118	-	30,000	-	30,000	-

Item	1993 Actual		1994 Estimated		1995 Estimated	
	Amount	Staff- Years	Amount	Staff- Years	Amount	Staff- Years
Human Nutrition Information Service: for administrative support.....	95,194	--	95,000	--	95,000	--
for systems furniture.....	280,000	--	--	--	--	--
Office of International Cooperation and Dev.: for employee services and training and animal damage control.....	643,240	--	709,000	--	709,000	--
Office of Inspector Gen.: for administrative support.....	19,341	--	20,000	--	20,000	--
Office of Personnel Management: for the Presidential Management Intern Program.....	4,000	--	--	--	--	--
Packers and Stockyards Administration: for administrative support.....	287,750	6	288,000	6	288,000	6
Total, Other Agriculture Appropriations.....	4,611,863	68	4,326,000	67	4,179,000	64
Total, Agriculture Appropriations.....	474,619,267	6,037	466,507,000	6,014	447,551,000	6,024
<u>Other Federal Funds:</u>						
Department of Energy: for animal damage control activities.....	29,505	--	30,000	--	30,000	--
Department of the Interior: Fish and Wildlife Service: for animal damage control activities.....	284,414	--	300,000	--	300,000	--
Bureau of Land Management: for animal damage control activities...	15,000	--	15,000	--	15,000	--
National Park Service: for animal damage control activities.....	146,885	--	150,000	--	150,000	--
Department of Treasury: for shuttle service.....	69,147	--	--	--	--	--
Federal Aviation Administration: for animal damage control activities...	300,000	--	300,000	--	300,000	--
Forest Service: for animal damage control and gypsy moth control.....	336,195	--	300,000	--	300,000	--
Tennessee Valley Authority: for animal damage control activities...	108,135	--	110,000	--	110,000	--

Item	1993 Actual		1994 Estimated		1995 Estimated	
	Amount	Staff- Years	Amount	Staff- Years	Amount	Staff- Years
U.S. Air Force: for animal damage control activities.....	87,447	—	90,000	—	90,000	—
U.S. Army: for animal damage control activities.....	961,109	—	950,000	—	950,000	—
U.S. Navy: for preclearance activities.....	85,000	—	85,000	—	85,000	—
for animal damage control activities.....	1,229,706	—	1,300,000	—	1,300,000	—
Total, Other Federal Funds	3,652,543	—	3,630,000	—	3,630,000	—
Total, Federal Funds.....	478,271,810	6,037	470,137,000	6,014	451,181,000	6,024
<u>Reimbursements:</u>						
Funds from State and local governments for animal damage control activities...	6,889,798	219	7,000,000	290	7,000,000	185
California Department of Food and Agriculture: for inspection services.....	2,406,873	51	2,400,000	51	2,400,000	51
for pink bollworm facility.....	1,305,000	—	1,305,000	—	1,305,000	—
Illegally imported birds.....	144,720	—	150,000	—	150,000	—
Import-Export user fees....	1,017,220	20	3,025,000	50	4,200,000	72
Phytosanitary certificate user fees.....	2,913,642	9	3,243,000	12	3,502,000	15
Reimbursable overtime.....	9,619,363	—	10,183,000	—	10,997,000	—
Truman Animal Import Center.....	1,616,330	—	1,200,000	—	1,200,000	—
Veterinary diagnostics user fees.....	73,626	—	980,000	—	980,000	—
<u>Trust Funds:</u>						
Feed, care, and attendants for animals in quarantine...	2,569,250	23	2,397,000	23	2,397,000	23
Miscellaneous Contributed Funds.....	3,048,750	30	4,524,000	30	4,524,000	30
Total, Non-Federal Funds..	31,604,572	352	36,407,000	456	38,655,000	376
Total, Animal and Plant Health Inspection Service..	509,881,008	6,389	506,544,000	6,470	489,836,000	6,400

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Permanent Positions by Grade and Staff-Year Summary1993 and Estimated 1994 and 1995

Grade	1993			1994			1995		
	Headquarter	Field	Total	Headquarter	Field	Total	Headquarter	Field	Total
ES-5	5	4	9	6	2	8	6	2	8
ES-4	4	5	9	5	5	10	5	5	10
ES-3	0	2	2	2	1	3	2	1	3
ES-2	1	0	1	1	1	2	1	1	2
ES-1	1	0	1	2	0	2	2	0	2
GS-15	50	27	77	46	25	71	45	25	70
GS-14	165	129	294	163	127	290	160	125	285
GS-13	155	259	414	152	258	410	149	256	405
GS-12	107	589	696	108	597	705	107	591	698
GS-11	110	771	881	116	781	897	114	773	887
GS-10	3	6	9	3	6	9	3	6	9
GS-09	54	805	859	59	815	874	58	807	865
GS-08	103	175	278	107	177	284	106	175	281
GS-07	47	371	418	51	381	432	50	377	427
GS-06	80	181	261	81	183	264	80	182	262
GS-05	82	494	576	83	502	585	82	497	579
GS-04	42	296	338	43	300	343	42	297	339
GS-03	11	20	31	11	20	31	11	20	31
GS-02	0	2	2	0	2	2	0	2	2
Other Graded Positions.....	12	355	367	12	360	372	12	348	360
Ungraded Positions	0	114	114	0	115	115	0	114	114
Total Permanent Positions	1,032	4,605	5,637	1,051	4,658	5,709	1,035	4,604	5,639
Unfilled Positions End-of-Year.....	-81	-399	-480	-85	-403	-488	-85	-403	-488
Total, Permanent Employment, End-of-Year.....	951	4,206	5,157	966	4,255	5,221	950	4,201	5,151
Staff-Years:									
Ceiling.....	1,014	5,375	6,389	1,027	5,443	6,470	1,016	5,384	6,400

ANIMAL AND PLANT HEALTH INSPECTION SERVICE
CLASSIFICATION BY OBJECTS

1993 and Estimated 1994 and 1995

	<u>1993</u>	<u>1994</u>	<u>1995</u>
Personnel Compensation:			
Headquarters.....	\$46,428,060	\$43,238,400	\$39,098,000
Field.....	<u>185,712,239</u>	<u>172,953,600</u>	<u>156,392,000</u>
11 Total personnel compensation.....	232,140,299	216,192,000	195,490,000
12 Personnel benefits.....	47,298,654	48,520,000	43,350,000
13 Benefits for former personnel.....	<u>1,460,690</u>	<u>816,000</u>	<u>700,000</u>
Total personnel compensation and benefits.....	280,899,643	265,528,000	239,540,000
Other Objects:			
21 Travel.....	15,121,549	13,707,000	14,761,000
22 Transportation of things.....	4,416,484	4,487,000	4,489,000
23.2 Rental payments to others.....	3,650,021	3,645,000	3,633,000
23.3 Communications, utilities and miscellaneous charges.....	15,306,756	15,416,000	16,115,000
24 Printing and reproduction	1,392,599	598,000	700,000
25.2 Other services.....	57,849,522	63,006,000	75,030,000
26 Supplies and materials...	24,635,658	26,878,000	26,708,000
31 Equipment.....	10,261,873	27,602,000	26,422,000
32 Lands and structures....	10,028	27,000	27,000
41 Grants, contributions and subsidies.....	21,996,287	26,494,000	23,668,000
42 Insurance claims and indemnities.....	2,613,971	4,626,000	5,285,000
43 Interest and dividends...	<u>21,035</u>	<u>22,000</u>	<u>21,000</u>
Total other objects.....	<u>157,275,783</u>	<u>186,508,000</u>	<u>196,859,000</u>
Total direct obligations.....	<u>438,175,426</u>	<u>452,036,000</u>	<u>436,399,000</u>

Position Data:

Average Salary, ES positions...	\$103,000	\$106,811	\$108,947
Average Salary, GM/GS positions.....	39,500	40,960	41,667
Average grade, GM/GS positions.	8.61	8.61	8.61

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

The estimates include appropriation language for this item as follows (new language is underscored; deleted matter is enclosed in brackets):

Salaries and Expenses:

For expenses, not otherwise provided for, including those pursuant to the Act of February 28, 1947, as amended (21 U.S.C. 114b-c), necessary to prevent, control, and eradicate pests and plant and animal diseases; to carry out inspection, quarantine, and regulatory activities; to discharge the authorities of the Secretary of Agriculture under the Act of March 2, 1931 (46 Stat. 1468; 7 U.S.C. 426-426b); and to protect the environment, as authorized by law, [\$439,564,000,] \$334,539,000, [of which \$91,460,000 shall be derived from user fees deposited in the Agricultural Quarantine Inspection User Fee Account, and] of which \$4,938,000, to remain available until expended, for the control of outbreaks of insects, plant diseases, animal diseases and for control of pest animals and birds to the extent necessary to meet emergency conditions: and of which \$3,500,000 shall be for the Integrated Systems Acquisition Project, to remain available until expended: Provided, That [if the demand for Agricultural Quarantine Inspection (AQI) user fee financed services is greater than expected and/or other uncontrollable events occur, the Agency may exceed the AQI User Fee limitation by up to 10 per centum, provided such funds are available in the Agricultural Quarantine Inspection User Fee Account, and with notification to the Appropriation Committees:] in fiscal year 1995 and thereafter, fees collected and deposited in the Agricultural Quarantine Inspection User Fee Account shall be available for authorized purposes without further appropriation: Provided further, That in fiscal year 1995 and thereafter, the Agency is authorized to collect fees for the total direct and indirect costs of technical assistance, goods, or services provided to States, other political subdivisions, domestic and international organizations, foreign governments, or individuals, such fees shall be credited to this account, to remain available until expended, without further appropriation, for providing such assistance, goods, or services: Provided further, That no funds shall be used to formulate or administer a brucellosis eradication program for the current fiscal year that does not require minimum matching by the States of at least 40 per centum: Provided further, That this appropriation shall be available for field employment pursuant to the second sentence of section 706(a) of the Organic Act of 1944 (7 U.S.C. 2225), and not to exceed \$40,000 shall be available for employment under 5 U.S.C. 3109: Provided further, That this appropriation shall be available for the operation and maintenance of aircraft and the purchase of not to exceed four, of which two shall be for replacement only: Provided further, That, in addition, in emergencies which threaten any segment of the agricultural production industry of this country, the Secretary may transfer from other appropriations or funds available to the agencies or corporations of the Department such sums as he may deem necessary, to be available only in such emergencies for the arrest and eradication of contagious or infectious disease of pests or animals, poultry, or plants, and for expenses in accordance with the Act of February 28, 1947, as amended, and section 102 of the Act of September 21, 1944, as amended, and any unexpended balances of funds transferred for such emergency purposes in the next preceding fiscal year shall be merged with such transferred amounts: Provided further, That appropriations hereunder shall be available pursuant to law (7 U.S.C. 2250) for the repair and alteration of leased buildings and improvements, but unless otherwise provided the cost of altering any one building during the fiscal year shall not exceed 10 per centum of the current replacement value of the building.

The first change provides no-year authority for the contingency fund. This was previously shown in Section 706 of the General Provisions.

The second change provides no-year authority for the Integrated Systems Acquisition Project. This was previously shown in Section 706 of the General Provisions.

The third change would allow APHIS to provide increased AQI services as the demand for international commerce and travel grows. Under existing legislation, AQI obligations are subject to appropriation limitations. As the demand for inspection services increases, APHIS needs to increase staffing to match actual levels of international commerce and travel.

The fourth change would give APHIS authority to recover the direct and indirect costs of providing goods and services, such as training, scientific instruments not available commercially, and other direct assistance requested by States, local jurisdictions, public and private organizations, international organizations, foreign governments, and individuals, when providing technical assistance, goods, and services is in accordance with the purposes of this appropriation.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

SALARIES AND EXPENSES

Appropriations Act, 1994	\$439,564,000
Budget Estimate, 1995	<u>436,399,000</u>
Decrease in Appropriation	<u>-3,165,000</u>

SUMMARY OF INCREASES AND DECREASES

(On basis of adjusted appropriation)

Item of Change	1994 Estimated	Pay Cost	Other Changes	1995 Estimated
AQI Appropriated.....	\$24,246,000	+ \$251,000	+ \$643,000	\$25,140,000
AQI User Fees.....	91,460,000	+ 743,000	+ 9,657,000	101,860,000
Foot-and-mouth disease.....	4,046,000	+ 5,000	-56,000	3,995,000
Import/Export Inspection.....	6,800,000	+ 53,000	-318,000	6,535,000
International Programs.....	5,826,000	+ 26,000	+ 254,000	6,106,000
Mediterranean Fruit Fly Exclusion.....	10,199,000	+ 30,000	-140,000	10,089,000
Mexican Fruit Fly.....	2,272,000	+ 11,000	-127,000	2,156,000
Screwworm.....	34,645,000	+ 44,000	-660,000	34,029,000
Animal Health Monitor. & Surv....	59,933,000	+ 272,000	-824,000	59,381,000
Animal & Plt Hlth. Reg.Enforce..	5,849,000	+ 53,000	-37,000	5,865,000
Fruit Fly Detection.....	3,950,000	+ 28,000	-55,000	3,923,000
Pest Detection.....	3,444,000	+ 30,000	732,000	4,206,000
ADC Operations.....	26,092,000	+ 223,000	-2,884,000	23,431,000
Aquaculture.....	0	0	+ 493,000	493,000
Biocontrol.....	5,702,000	+ 52,000	+ 2,000,000	7,754,000
Boll Weevil.....	13,226,000	+ 39,000	-181,000	13,084,000
Brucellosis.....	31,004,000	+ 122,000	-5,374,000	25,752,000
Cattle Ticks.....	4,597,000	+ 45,000	-64,000	4,578,000
Golden Nematode.....	658,000	+ 6,000	-49,000	615,000
Gypsy Moth.....	5,203,000	+ 46,000	-72,000	5,177,000
Honey Bee Pest.....	380,000	0	-380,000	0
Imported Fire Ant.....	2,700,000	0	-2,700,000	0
Misc. Pests & Diseases.....	1,996,000	+ 20,000	-28,000	1,988,000
Noxious Weeds.....	475,000	+ 2,000	-73,000	404,000
Pink Bollworm.....	2,292,000	+ 9,000	-1,232,000	1,069,000
Pre-Harvest Program.....	0	0	+ 5,702,000	5,702,000
Pseudorabies.....	4,543,000	+ 19,000	-1,145,000	3,417,000
Russian Wheat Aphid.....	2,400,000	0	-2,400,000	0
Salmonella Enteritidis.....	3,411,000	+ 20,000	-47,000	3,384,000
Scrapie.....	3,000,000	+ 10,000	-41,000	2,969,000
Sweet Potato Whitefly.....	3,514,000	0	-3,514,000	0
Tropical Bont Tick.....	0	0	+ 537,000	537,000
Tuberculosis.....	5,538,000	+ 38,000	-77,000	5,499,000
Witchweed.....	4,081,000	+ 9,000	-2,115,000	1,975,000
Animal Welfare.....	9,262,000	+ 73,000	-132,000	9,203,000
Horse Protection.....	481,000	+ 3,000	-122,000	362,000
ADC Methods Development.....	9,681,000	+ 61,000	-390,000	9,352,000

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<u>Item of Change</u>	1994 <u>Estimated</u>	<u>Pay Cost</u>	Other <u>Changes</u>	1995 <u>Estimated</u>
Biotechnology Environmental				
Protection.....	7,756,000	+46,000	-112,000	7,690,000
Plant Methods Development Labs..	5,084,000	+52,000	-77,000	5,059,000
Veterinary Biologics.....	10,434,000	+81,000	-144,000	10,371,000
Veterinary Diagnostics.....	14,946,000	+71,000	-206,000	14,811,000
All Other.....	<u>8,438,000</u>	<u>0</u>	<u>0</u>	<u>8,438,000</u>
Total, Salaries & Expenses.....	<u>439,564,000</u>	<u>+2,593,000</u>	<u>-5,758,000</u>	<u>436,399,000</u>

PROJECT STATEMENT
(On Basis of Appropriation)

Project	1993 Actual		1994 Estimated		Increase or Decrease	1995 Estimated	
	Amount	Staff- Years	Amount	Staff- Years		Amount	Staff- Years
1. Pest and disease exclusion:							
(a) Agricultural quarantine inspection (Appropriated)....	\$23,742,021	546	\$24,246,000	600	\$894,000	\$25,140,000	618
(b) Agricultural quarantine inspection (User fees).....	83,362,000	1,529	91,460,000	1,604	10,400,000	101,860,000	1,838
(c) Foot-and-mouth disease.....	4,226,198	10	4,046,000	11	-51,000	3,995,000	10
(d) Import-Export inspection.....	11,163,785	148	6,800,000	91	-265,000	6,535,000	89
(e) International programs.....	4,366,211	46	5,826,000	50	280,000	6,106,000	49
(f) Mediterranean fruit fly.....	10,424,824	69	10,199,000	73	-110,000	10,089,000	70
(g) Mexican fruit fly.....	2,137,046	21	2,272,000	25	-116,000	2,156,000	23
(h) Screwworm.....	31,167,301	87	34,645,000	91	-616,000	34,029,000	82
Total, Pest and Disease Exclusion.....	170,589,386	2,456	179,494,000	2,545	(1)	189,910,000	2,779
2. Plant and animal health monitoring:							
(a) Animal health monitoring & surveillance.....	59,378,000	636	59,933,000	657	-552,000	59,381,000	643
(b) Animal and plant health regulatory enforcement.....	5,623,823	125	5,849,000	129	16,000	5,865,000	117
(c) Fruit fly detection.....	3,233,202	49	3,950,000	51	-27,000	3,923,000	50
(d) Pest detection.....	4,281,942	60	3,444,000	53	762,000	4,206,000	58
Total, Plant and animal health monitoring.....	72,516,967	870	73,176,000	890	(2)	73,375,000	868
3. Pest and disease management:							
(a) Animal damage control operations.....	25,568,147	511	26,092,000	525	-2,661,000	23,431,000	482
(b) Aquaculture.....	—	—	—	—	493,000	493,000	6
(c) Biocontrol.....	5,038,081	105	5,702,000	114	2,052,000	7,754,000	124
(d) Boll weevil.....	10,089,239	100	13,226,000	95	-142,000	13,084,000	96
(e) Brucellosis.....	30,356,655	277	31,004,000	255	-5,252,000	25,752,000	197
(f) Cattle ticks.....	6,216,057	133	4,597,000	135	-19,000	4,578,000	104
(g) Golden nematode.....	644,036	14	658,000	13	-43,000	615,000	12
(h) Grasshopper and Mormon cricket.....	3,178,714	52	—	55	—	—	34
(i) Grasshopper and Mormon cricket: no-year.....	3,292,460	—	—	—	—	—	—
(j) Gypsy moth.....	4,479,802	101	5,203,000	104	-26,000	5,177,000	98
(k) Honeybee pests.....	283,255	10	380,000	8	-380,000	—	—
(l) Imported fire ant.....	3,475,158	24	2,700,000	—	-2,700,000	—	—
(m) Miscellaneous plant disease.....	2,135,211	34	1,996,000	39	-8,000	1,988,000	31
(n) Noxious weeds.....	637,862	23	475,000	3	-71,000	404,000	3
(o) Pink bollworm.....	2,870,127	24	2,292,000	18	-1,223,000	1,069,000	17
(p) Pre-harvest pathogen reduction.....	—	—	—	—	5,702,000	5,702,000	54
(q) Pseudorabies.....	3,678,046	48	4,543,000	33	-1,126,000	3,417,000	40
(r) Russian wheat aphid.....	1,920,104	11	2,400,000	12	-2,400,000	—	—
(s) <i>Salmonella enteritidis</i>	2,698,747	48	3,411,000	48	-27,000	3,384,000	41
(t) Scrapie.....	746,851	13	3,000,000	32	-31,000	2,969,000	25
(u) Sweet potato whitefly.....	2,583,022	38	3,514,000	47	-3,514,000	—	—
(v) Tropical bont tick.....	—	—	—	—	537,000	537,000	3
(w) Tuberculosis.....	3,933,216	52	5,538,000	56	-39,000	5,499,000	60
(x) Witchweed.....	5,588,081	59	4,081,000	32	-2,106,000	1,975,000	17
Total, Pest and disease management.....	119,412,871	1,677	120,812,000	1,624	(3)	107,828,000	1,444

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Project	1993 Actual		1994 Estimated		Increase or Decrease	1995 Estimated	
	Amount	Staff- Years	Amount	Staff- Years		Amount	Staff- Years
4. Animal care:							
(a) Animal welfare.....	9,414,220	172	9,262,000	177	-59,000	9,203,000	171
(b) Horse protection.....	382,191	7	481,000	6	-119,000	362,000	6
Total, Animal care.....	9,796,411	179	9,743,000	183	-178,000	9,565,000	177
5. Scientific and technical services:					(4)		
(a) Animal control methods development.....	9,551,637	122	9,681,000	125	-329,000	9,352,000	119
(b) Biotechnology environmental protection.....	7,685,841	91	7,756,000	92	-66,000	7,690,000	98
(c) Integrated systems acquisition project.....	2,098,798	5	3,500,000	17	-	3,500,000	17
(d) Plant methods development labs.....	5,191,236	104	5,084,000	107	-25,000	5,059,000	105
(e) Veterinary biologics.....	9,772,190	181	10,434,000	191	-63,000	10,371,000	184
(f) Veterinary diagnostics.....	14,285,314	169	14,946,000	173	-135,000	14,811,000	169
Total, Scientific and technical services.....	48,585,016	672	51,401,000	705	-618,000	50,783,000	692
6. Contingencies: plant and animal diseases and pests.....	5,838,672	-	4,938,000	-	-	4,938,000	-
7. Transfer to the Office of the Secretary.....	-212,000	-	-	-	-	-	-
Unobligated balance available start-of-year.....	-22,731,000	-	-	-	-	-	-
Unobligated balance available end-of-year.....	35,663,000	-	-	-	-	-	-
Unobligated balance expiring.....	1,086,000	-	-	-	-	-	-
Total, Available or estimate, salaries and expenses.....	440,545,323	5,854	439,564,000	5,947	-3,165,000	436,399,000	5,960
8. CCC transfer (fruit fly and Asian gypsy moth.....)	16,094,304	115	-	-	-	-	-
9. From FNS for cattle tick.....	10,825,000	-	12,472,000	-	-12,472,000	-	-
10. Advances and Reimbursements:							
(a) Federal.....	8,264,406	68	7,956,000	67	-147,000	7,809,000	64
(b) Non-Federal.....	25,986,572	299	29,486,000	403	2,248,000	31,734,000	323
Total, Advances and Reimbursements.....	34,250,978	367	37,442,000	470	2,101,000	39,543,000	387
Total, Available or estimate.....	501,715,605	6,336	489,478,000	6,417	-13,536,000	475,942,000	6,347

No-Year and Emergency Programs

Project	1993 Actual	1994 Carry-Over	1994 Appropriated	1994 Available
Animal Damage Control.....	5,988,955	900,842	-	900,842
Boll weevil.....	10,089,239	3,045,761	13,226,000	16,271,761
Grasshopper/Mormon Cricket reserve fund.....	3,292,460	13,267,552	-	13,267,552
10% of Screwworm.....	2,437,852	1,026,648	3,465,000	4,491,648
Contingency Fund.....	5,838,671	2,086,662	4,938,000	7,024,662
Fruit flies.....	13,476,983	12,530,471	-	12,530,471
Asian Gypsy Moth.....	1,328,733	739,918	-	739,918
ISAP.....	2,098,817	1,837,189	3,500,000	5,337,189
Total.....	44,551,710	35,435,043	25,129,000	60,564,043

EXPLANATION OF PROGRAM

The Animal and Plant Health Inspection Service (APHIS) was established on April 2, 1972, pursuant to the authority of the Reorganization Plan No. 2 of 1953.

APHIS conducts cooperative programs with State and local agencies and organizations to control, eradicate, and prevent the movement of plant and animal diseases and pests. Inspection and regulatory programs prevent the introduction into the United States of pests and diseases of foreign origin and the spread of established pests within the country. Under the Federal Noxious Weed Act of 1974, the Agency carries out survey, regulatory, and control actions to protect American agriculture from the invasion and interstate spread of noxious weeds. APHIS, under the Endangered Species Act, regulates the import and export of designated endangered plant species and ensures that cooperative Federal-State pest control programs which utilize pesticides will not adversely affect endangered species. Under the Virus-Serum-Toxin Act, APHIS carries out activities to prevent the production and distribution of contaminated, dangerous, or harmful veterinary biologics. Under the authority of the Animal Welfare Act as amended, the Agency conducts activities to ensure that certain animals intended for use in research or for exhibition purposes are provided with humane care and treatment, to assure humane treatment of animals during transportation in commerce, and to prevent the sale or use of animals which have been stolen. APHIS, under the authority of the Horse Protection Act, works to prevent the interstate movement or exhibition of horses which have been "sored." Under the Swine Health Protection (SHP) Act, the Agency conducts a Federal-State program to control the feeding of raw food waste to swine. APHIS, under the authority of the Animal Damage Control Act of 1931, researches and carries out cooperative programs to control wildlife-caused losses to agriculture, safety hazards at airports, and public nuisances in a variety of areas. APHIS, under authority of the Plant Pest Act, Plant Quarantine Act, and Virus-Serum-Toxin Act coordinates the development and implementation of the Department's regulation and evaluation of applications of a number of biotechnologically derived products for test permits and commercial licenses.

The APHIS "Salaries and Expenses" appropriation and user fees fund the following activities:

1. Pest and Disease Exclusion Programs -- APHIS carries out inspections at U.S. ports-of-entry to prevent the introduction of foreign plant and animal pests and diseases which are harmful to our country's agriculture. APHIS develops and conducts preclearance programs to ensure that foreign agricultural products destined for the United States do not present a risk to U.S. agriculture. APHIS engages in cooperative programs to control pests of imminent concern to the United States and to strengthen foreign plant protection and quarantine organizations. APHIS also certifies plants and plant products for export and regulates imports and exports of designated endangered plant species. APHIS assists U.S. exporters and the Foreign Agricultural Service in revising foreign plant and animal import regulations to encourage and increase U.S. agricultural exports.

The statutory authority supporting this program is contained in 7 U.S.C. 148 and 150aa-150jj; 19 U.S.C. 1306; and 21 U.S.C. 102, 111-120, 121-123, 127, and 135-135b. The principal legislative authorities for these activities include the Organic Act of 1944, as amended by P.L. 94-231, enacted March 15, 1976; the Plant Quarantine Act of 1912; and the Mexican Border Act of 1942. The Department's enforcement responsibilities for endangered plants are contained in the Endangered Species Act of 1973. The Airport and Airways Development Act, P.L. 94-353, Section 15(c), was enacted July 12, 1976. Section 2509 of the Food, Agriculture, Conservation, and Trade Act (Farm Bill) of 1990 as amended by Section 1203 of the 1991 Budget

Reconciliation Bill authorizes user fees for agricultural quarantine inspection and import-export inspection. The activities carried out in the pest and disease exclusion programs are as follows:

- Agricultural Quarantine Inspection (AQI) - The purpose of the AQI program is to protect American agriculture from exotic pests and diseases and to facilitate the entry of United States agricultural products into international markets. The program carries out its mission by inspecting the increasing amount of cargo and international air and sea passengers at ports-of-entry and pre-clearance locations overseas. The AQI program also conducts inspections of cargo and people at the Mexican and Canadian borders. APHIS continues to implement innovative inspection techniques such as X-ray machines and detector dog teams to handle the increasing workload. Pre-clearance of agricultural products at foreign locations is another means of dealing with this increasing workload without increasing risk to U.S. Agriculture. The use of X-ray technology for passenger baggage has increased efficiency in passenger inspections. The detector dog teams are used at international airports and post offices for baggage and package inspections and have a success rate of 80 percent in finding concealed regulated items.

In cooperation with the U.S. Customs Service and the Department of Defense, APHIS conducts military preclearance operations in all the major military commands. The purpose of the military preclearance programs is to inspect troops and their personal gear and to clean military vehicles and other cargo prior to return to the United States. APHIS officers provide assistance, advice, and oversight in advisory roles to military commands, as well as acting as advisors to a number of military exercises each year.

- Foot-and-Mouth Disease (FMD) - The purpose of the FMD program is to prevent the disease in South America from entering Panama, Central America, Mexico, and the United States. An FMD eradication program is continuing in northern Colombia. Program methods include surveillance, inspection, quarantine, vaccination, and emergency preparedness. Cooperative FMD prevention agreements, using surveillance, disease investigation, and emergency preparedness are being maintained with Mexico, Panama, and all of the Central American countries. In addition, the Mexico program conducts prevention activities for all foreign animal diseases (FAD) including African horse sickness, African swine fever, and avian influenza. The Mexico and Panama programs are maintaining high containment diagnostic laboratories. FMD is one of the most costly multi-host animal diseases. Estimates show that 15-year losses of more than \$20 billion could occur if FMD were to re-enter the United States.

- Import/Export Inspection - This program protects domestic livestock, poultry, and wildlife from restricted diseases, including those transmissible from animals to humans. APHIS regulates the importations of animals and animal products and promotes markets abroad by ensuring that U.S. origin animals and animal products meet health and welfare requirements of recipient countries.

Import Animals - This program ensures that all imported animals, germplasm, birds, and poultry meet United States health requirements. Principal methods include inspecting and approving zoos, conveyances, and entry ports; maintaining the Harry S Truman Animal Import Center in Key West, Florida; and intercepting smuggled animals and animal products.

Export Animals - The goal of the export animals program is to ensure that all certifications of being freed from contagious diseases comply with USDA health agreements with importing countries. This function is vital to the protection and expansion of the \$6 billion U.S. animal and germ plasm export market.

Animal Products, Import and Export - Control of animal products involves prohibiting fresh, chilled, or frozen meats, and fresh milk from countries where rinderpest and FMD exist, and restricting chilled or frozen pork from countries with hog cholera, African swine fever, and swine vesicular disease. This ban includes commercial shipments of meat, hides, skins, trophies, glands, and animal products used in research and pharmaceutical manufacture. There are restrictions on food in the mail and in travelers' baggage and on garbage and leftover foods on aircraft and ships. APHIS enforces these restrictions at U.S. entry ports and controls importations of disease-causing agents (organisms and vectors) for research or vaccine manufacture, and laboratory animals inoculated with exotic agents.

FY 1994 import-export program plans include: (1) continued development of the National Center for Import and Export; (2) implementation of international agreements on regionalization and risk assessment-based import/export requirements; (3) preparation for regulating import and export of fish and aquaculture products; (4) further implementation of user fees for import and export services; and (5) revising regulations concerning importations of semen and embryos.

- **International Programs** - The objective of International Programs is to protect United States agriculture and to promote the export of U.S. agricultural products by actively addressing pest and disease problems at their origin rather than waiting for them to arrive at our ports of entry and borders. Through International Programs, APHIS maintains a presence in countries that are significant agricultural trading partners and may also be potential sources of economically dangerous agricultural pests and diseases. APHIS personnel at overseas locations, either on permanent assignment or short-term detail, provide an effective first line of defense against the entry of foreign plant and animal diseases and pests into our country. Their presence also facilitates the export of U.S. agricultural products, and promotes the exchange of science and technology in animal and plant health, by identifying and eliminating non-tariff trade barriers to agricultural products. They provide a timely link to sanitary and phytosanitary surveillance and to update diagnostic and disease/pest control strategies practiced by countries dealing with those conditions, facilitating a two-way exchange of technology.
- **Mediterranean Fruit Fly (Medfly)** - The objective of the program is to prevent sustained Medfly infestations from occurring in the continental United States, Virgin Islands, Puerto Rico, Mexico, and north of the 16° N. latitude in Central America. The Medfly, which is found throughout most of Central America, is one of the world's most destructive pests of fruits and vegetables. It is capable of becoming established in fruit and vegetable growing regions in the continental United States. Approximately 80 percent of U.S. citrus production is susceptible to Medfly. The presence of Medfly in Mexico would pose a serious threat to the United States, due to Mexico's location and its importance as a major source of winter fruits and vegetables for the United States. APHIS is currently eradicating a localized outbreak that was detected in California in FY 1992. APHIS with some assistance from Hawaii and California, constructed a sterile fruit fly rearing facility in Waimanalo, Hawaii. The facility is capable of supplying 500 million sterile flies per week for emergency eradication programs.

All flies produced at the facility will be utilized in emergency eradication efforts in FY 1994. In FY 1993, more than 14 billion sterile flies were used in California. Almost 36 billion Medflies were produced in rearing facilities in Mexico and Guatemala for the cooperative Moscamed program. This joint program with Mexico and Guatemala protects the United States by preventing the northward spread of Medfly into Mexico.

- Mexican Fruit Fly (MFF) - The MFF, an insect pest of more than 40 species of fruit, periodically occurs in the United States, primarily in the lower Rio Grande Valley in southern Texas. Other citrus growing States such as Arizona, California, and Florida are vulnerable to MFF infestations either by migration of these flies across the northwestern border with Mexico, or from infested fruit being shipped to or through these States. Consequently, the program maintains suppression activities in the northwestern region of Mexico and regulatory programs in the lower Rio Grande Valley and adjacent portions of Mexico. Additional regulatory and suppression activities in the lower Rio Grande Valley in southern Texas, provide protection for the U.S. citrus industry. APHIS is currently conducting an eradication program in California. Sterile MFF's produced at the USDA facility in Mission, Texas, are being released to eliminate the pest.
- Screwworm - Screwworm eradication began as an experimental project in Florida during the 1950's. The program was so successful that by 1966 the United States was declared screwworm-free. Continued reintroduction from Mexico led to a 1972 cooperative agreement to eradicate the pest from Mexico and establish a permanent barrier at the Isthmus of Tehuantepec. The program reached that barrier in 1984. However, large cattle movements from infested areas further south resulted in a high risk of reinfestation. A Memorandum of Understanding signed in January 1987, allowed the Screwworm Commission to undertake efforts to move the barrier farther south.

The goal of the screwworm program is to prevent the reintroduction of the parasitic screwworm into the United States by eradicating this insect in Mexico and Central America and establishing a permanent sustainable sterile fly barrier in Panama. In 1985, APHIS conducted a feasibility study of screwworm eradication in Central America. This study identified the Isthmus of Panama and the Guatemala/Honduras border as cost-beneficial locations for a permanent, sustainable sterile fly barrier.

Mexico was declared screwworm-free on February 25, 1991. On January 22, 1992, a mature screwworm larvae was collected in the Mexican State of Campeche. Subsequently, 61 additional cases were reported in the southern Mexican States of Campeche, Chiapas, Tabasco, Veracruz, and the northern State of Tamaulipas near Ciudad Victoria which is only 121 miles south of the United States-Mexican border. Illegal and legal importation of cattle without inspection or quarantine has been identified as the probable source of the infestations.

In spite of delays incurred by the screwworm program as a result of the outbreak in Mexico, the program has continued to make progress in Central America. Belize, Guatemala, and El Salvador are considered to be free of self-sustaining screwworm populations. El Salvador was declared technically free at a ceremony in San Salvador in October 1993. Also in October 1993, USDA was able to enter into a cooperative agreement for the eradication of screwworms in Costa Rica. Currently, the program is carrying out eradication activities in Honduras and Nicaragua. A cooperative agreement with Panama is planned for FY 1994.

The levels of pest and disease exclusion activities are shown by the selected examples that follow:

Program	1993 Actual	1994 Estimated	1995 Estimated
Agricultural quarantine inspection:			
Passenger inspections (millions).....	57	58	59
Pest interceptions (thousands).....	52	53	54
Plant and animal product and byproduct inspection:			
Airplanes (thousands).....	377	390	400
Vessels (thousands).....	48	50	51
Plant units processed (millions).....	456	460	465
Regulated and miscellaneous cargo inspections conducted (thousands).....	973	990	995
Phytosanitary export certification:			
Certificates issued (thousands).....	261	262	263
Interceptions (thousands):			
Unauthorized plant material.....	1,474	1,600	1,650
Unauthorized animal products/byproducts.....	239	245	247
Unauthorized material:			
Mail.....	5,815	5,950	6,000
Baggage.....	1,064	1,150	1,200
Intercepted endangered plant species:			
Seized and placed into rescue centers.....	21,132	12,006	13,000
Seized and returned to country of export.....	237	300	400
Number of shipments of plants seized:			
Rescue centers.....	789	800	810
Returned to country of export.....	7	10	10
Foot-and-mouth disease:			
Exotic animal disease investigations in Mexico:			
Total investigations.....	696	600	450
Livestock investigations (excluding rabbits).....	396	300	250
Investigations on rabbits.....	300	300	200
Vesicular disease investigations:			
in Panama.....	17	20	20
in Colombia.....	290	400	400
in Central America.....	281	285	320
in Mexico.....	78	75	80
Laboratory samples processed:			
in Mexico (excluding rabbits).....	400	400	400
in Mexico (total).....	700	2,200	2,500
in Panama.....	320	300	300
Import-Export program:			
Import inspection:			
Animals (thousands).....	4,401	4,000	4,000
Personally owned pet birds.....	1,386	1,500	1,500
Commercial birds.....	133,435	120,000	120,000
Poultry (chick and poult - thousands).....	6,282	7,000	7,000
Poultry hatching eggs (thousands).....	17,593	18,000	18,000
Bovine, sheep, and horse semen doses.....	325,000	300,000	300,000
Goat and bovine embryos.....	1,920	1,000	1,000
Export inspection:			
Ruminants and horses (thousands).....	743	1,000	1,000
Poultry (thousand).....	9,398	15,000	15,000
Dozens of hatching eggs (thousands).....	10,307	20,000	20,000
Bull semen (thousands).....	1,383	1,300	1,300
Bovine embryos.....	1,725	2,000	2,500
New agreements with foreign countries to accept animal/poult exported from U.S.....	11	12	13
Outbreaks of exotic animal diseases due to importations.....	-	-	-
Import/Export products:			
Import product permits.....	1,786	2,000	2,000
Organism and vector permits.....	4,456	4,700	5,000
Product export certifications.....	5,000	5,500	6,000
Facility/establishment inspections.....	1,057	2,000	2,500
Laboratory inspections.....	636	750	825

Program	1993 Actual	1994 Estimated	1995 Estimated
Mediterranean fruit fly:			
Sterile insects released (millions):			
California.....	14,375	16,100	18,200
Hawaii.....	1,500	—	—
Guatemala.....	17,239	18,000	20,000
Mexico.....	12,743	11,000	9,000
Sterile insects produced (millions):			
Guatemala.....	8,660	8,800	13,000
Mexico.....	26,631	27,500	28,000
Hawaii.....	18,408	26,000	26,000
Jackson traps serviced by USDA (thousands):			
Mexico.....	15,871	16,000	16,000
Medfly detection sites:			
Mexico.....	119	125	125
Peten, Guatemala.....	3	3	5
Belize.....	1	—	—
Mexican fruit fly:			
Sterile insects released (millions)			
Northwest Mexico.....	489	546	546
Northeast Mexico.....	25	25	25
California.....	170	780	0
Texas.....	760	960	960
McPhail traps serviced by USDA:			
Mexico.....	5,088	5,100	5,100
Medfly detection sites:			
Baja California Norte.....	74	50	40
Lower Rio Grande (Mexico).....	8	—	—
Sonora Free Zone.....	3	—	—
Screwworm:			
Cases in the United States.....	—	—	—
Cases in Mexico.....	5	—	—
Cases in Guatemala.....	5	—	—
Cases in Belize.....	—	—	—
Cases in El Salvador.....	157	—	—
Cases in Honduras.....	2,961	300	—
Cases in Nicaragua.....	28,182	17,000	6,000
Cases in Costa Rica.....	—	50	4,400
Cases in Panama.....	—	—	300
Sterile fly production - Tuxtla Gutierrez, Mexico (millions/week).....	260	250	300

2. Plant and animal health monitoring programs -- The plant and animal health monitoring programs are primarily cooperative efforts of the Federal and State governments, and industry. APHIS conducts programs to prevent communicable plant and animal diseases of foreign origin from entering the United States. Upon entrance into this country, the pests and diseases are rapidly diagnosed. The Agency also carries out surveys in cooperation with the States to detect harmful plant and animal pests and diseases. The programs also help determine if there is a need to establish new pest or disease eradication programs.

The statutory authority for this work is contained in 7 U.S.C. 15, 17, 30, 54, 391, 429, and 3801; 15 U.S.C. 44; 19 U.S.C. 4; 21 U.S.C. 4, 5, and 45; 46 U.S.C. 15; and 49 U.S.C. 20. Principal legislative authority for these activities is contained in the Act of May 29, 1884; Act of August 30, 1890; Act of February 2, 1903; Act of March 3, 1905; Act of June 17, 1930; Act of September 21, 1944; Act of February 28, 1947; Act of September 6, 1961; Act of July 2, 1962; and Public Law 97-46 of September 25, 1981; Act of October 14, 1982; Act of January 13, 1983; P.L. 99-198 of December 23, 1985.

- Animal Health Monitoring and Surveillance (AHM&S) - This program, which is a cooperative effort of Federal and State governments, industry, and academia, maintains the capability for consistent disease surveillance and detection, emergency disease preparedness and response, animal health monitoring, and epidemiological delivery. APHIS protects and

monitors the health of the Nation's livestock and poultry and maintains the capability to respond promptly and effectively to new and emerging health issues. It enables APHIS to rapidly eliminate outbreaks of foreign animal diseases (FAD), to assess the risk of new and emerging domestic animal health issues, to support APHIS control and eradication programs, and to enhance the quality, safety, and competitiveness of U.S. food animal products. APHIS also conducts disease surveillance and detection for brucellosis, pseudorabies, tuberculosis, and selected domestic swine and poultry diseases. The Four Regional Emergency Animal Disease Eradication Organizations respond to FAD outbreaks in livestock and poultry populations. Disease is detected and monitored by investigating reports of suspicious cases, such as, vesicular conditions, poultry diseases, encephalitic conditions, and others. The Agency conducts inspections at slaughter establishments, livestock markets, and other concentration points. In addition, APHIS conducts epidemiological investigations to determine the extent of diseases including collection and testing of blood samples, traceback, and adjacent herd testing.

APHIS directs animal health monitoring which requires national surveys of animal populations to determine how operational practices of producers affect animal health and productivity. Data is disseminated regarding the incidence, trends, and economic impact of diseases of food animals. APHIS uses this information to improve the health of livestock and poultry through various approaches including improved management practices, specific treatments, and prevention strategies. The Agency defines and predicts the health and economic consequences of animal disease events and suggests appropriate responses. APHIS collects and analyzes epidemiological data and serves as an information distribution center for State livestock agencies, industry, and the general public.

APHIS will continue to protect the \$17.5 billion poultry industry by conducting national surveillance to prevent the entry and spread of velogenic viscerotropic Newcastle disease, avian influenza, and exotic Salmonella enteritidis (Phage Type 4), and will provide technical advice to the industry on diseases of economic importance. The Agency will continue to provide a voluntary cooperative State-Federal-industry program to improve poultry and poultry products and control egg-transmitted and hatchery-disseminated diseases using research and technology. APHIS coordinated and supports the National Poultry Improvement Plan (NPIP) through laboratory support, regional and national conferences, publication of provisions, lists of participants, and statistical reports. As a result, breeding flocks and hatcheries are classified as being clean of specific poultry diseases, thereby enabling producers to purchase stocks that are tested clean of the diseases.

APHIS cooperates with the States to protect the Nation's \$10 billion swine industry from the introduction and spread of harmful foreign diseases. These diseases could be devastating to swine fed untreated garbage containing meat scraps which harbor the causative agents of these diseases. The Agency conducts inspections of garbage feeding facilities, searches for illegal garbage feeders, and surveillance for African swine fever and hog cholera by testing swine slaughter serum samples from high-risk areas. These activities break the disease chain by preventing uncooked meat scraps from re-entering the food chain. The primary activity in States where garbage feeding is allowed is the enforcement of regulations requiring the heat treatment of garbage to kill harmful organisms before the garbage is fed to swine. In FY 1994, APHIS will complete risk assessment studies to evaluate the Swine Health Protection (SHP) Act. APHIS assumes Primary Enforcement

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Responsibility (PER) when a State cannot adequately enforce the SHP Act or upon emergency declaration by the Secretary. The Agency can increase the frequency of inspections to at least quarterly and more often in cases where facilities are found to have chronic deficiencies. APHIS will increase search efforts for unlicensed food waste feeders by cooperating with Federal, State, and local government agencies that conduct public health inspections of food preparation establishments. In addition, the Agency will conduct several regional training courses to familiarize veterinarians and animal health technicians with the SHP Act and their responsibilities. Also, the Agency will complete work on an educational aid emphasizing the contraindication of feeding uncooked poultry to swine.

APHIS will continue protecting livestock in freed States from becoming reinfected with brucellosis. The Agency will continue providing industry with technical support to control and eradicate domestic endemic diseases of economic importance and to promote the export of animals and germplasm. In cooperation with FSIS, APHIS plans to further increase the rate of submissions of tuberculosis-like lesions found during slaughter inspections. A greater submission rate would help the program locate new herds through tracebacks. Also, the Agency will continue to conduct pseudorabies testing and surveillance to measure each State's progress through all five eradication stages. In addition, APHIS responds to numerous reports of new plant pest species in the United States each year by conducting delimiting surveys, control or eradication treatments, and by restricting the movement of commodities which could spread the pest. The Agency also conducts activities to control or eradicate several livestock diseases and parasites. Primary attention in recent years has been devoted to bovine spongiform encephalopathy (BSE), bluetongue, and several equine diseases.

APHIS will continue to provide industry with technical support to control and eradicate domestic endemic diseases of economic importance and to promote the export of animals and germplasm. FY 1994 plans include: (1) analyzing, interpreting, and communicating National Animal Health Monitoring System (NAHMS) beef cow/calf health and productivity audit results from 18 States with 70 percent of the U.S. beef cow/calf population; (2) assessing and communicating how preharvest cattle management practices affect food safety in general and specifically E. coli O157:H7 in groundbeef; (3) implementing the first national feedlot cattle monitoring in 13 States; (4) adding value to existing monitoring of chicken and turkey breeders through NPIP data by analysis and graphic interpretation of disease trends; (5) disseminating NAHMS dairy monitoring results, including information on Cryptosporidium, E. coli, and salmonella, and completing analyses under an E. coli follow-up study to estimate the prevalence of this pathogen on infected farms in pre-weaned and recently weaned heifers; (6) expanding disease surveillance capabilities of the Veterinary Diagnostic Laboratory Reporting System by interpreting and reporting diagnostic data submitted by 27 State laboratories from the 25 States; (7) designing the second national swine monitoring project, and the first national sheep monitoring project, both scheduled to be implemented in FY 1995; and (8) continuing ongoing monitoring and disease surveillance for swine, dairy cow/calf, beef cow/calf, feedlot cattle, and breeder and layer chickens.

- Animal and plant health regulatory enforcement - The goal of this program is to provide regulatory support to APHIS programs, and to provide technical advice and assistance to program officials in the interpretation and application of the Federal laws and regulations coming under the jurisdiction of the Agency. The Agency conducts

preliminary investigations to determine if Federal laws or regulations have been violated. APHIS officials review the investigations, and if necessary, submit cases to the Office of the General Counsel for criminal or civil prosecution. The Agency continues to monitor the status of cases, helps prepare witness lists, recommends professional witnesses, and serves as trial assistants to the Department attorneys.

- Fruit Fly Detection - The objective of this program is to provide for early detection of exotic fruit fly introductions and to prevent sustained infestations from occurring in the continental United States, Virgin Islands, and Puerto Rico. The program provides traps, lures, and equipment, as well as personnel to install and service traps for early detection of Medfly, MFF, Oriental fruit fly, melon fly, guava fruit fly, Queensland fruit fly, peach fruit fly, and other exotic fruit flies. Early detection of infestations can substantially reduce emergency funding required for eradicating larger infestations.
- Pest Detection - The pest detection program has three main functions. The first of these is to rapidly discover foreign plant pests before they become established in agricultural areas, thereby reducing pest control costs and preventing widespread agricultural damage. The program's second function is to provide information supporting export of U.S. agricultural products. The third function is to provide information supporting the management of pests.

APHIS works in cooperation with the States in a project called the Cooperative Agricultural Pest Survey (CAPS). As part of this program, the States enter the results of plant pest surveys into a national database known as the National Agricultural Pest Information System (NAPIS). Updated information entered by the States may be quickly retrieved by State Departments of Agriculture, State Land Grant Universities, and Federal Agencies. NAPIS data can support statements to foreign officials about the pest-free status of U.S. agricultural production areas and also help determine the need and effectiveness of pest eradication action programs.

The levels of plant and animal health monitoring activities are shown by the selected examples that follow:

Program	1993 Actual	1994 Estimated	1995 Estimated
Animal health monitoring and surveillance:			
States participating in NAHMS.....	37	39	42
Percent of U.S. livestock covered by NAHMS:			
Dairy.....	94	96	98
Beef-cow/calf.....	82	88	96
Swine.....	96	98	99
Sheep.....	78	86	98
Feedlot cattle.....	93	98	99
Brooder chickens/turkeys, based on NPPI data.....	—	99	99
Number of major livestock/ poultry commodities monitored.....	5	7	7
Producer voluntary participation rates in NAHMS national surveys.....	70	76	80
Veterinary Diagnostic Laboratory Reporting System:			
Number of states participating.....	22	25	27
Number of laboratories submitting data.....	25	28	31
Diseases and disease agents tracked.....	26	11	15
Number of States classified as U.S. Pullorum Typhoid Clean.....	40	41	40
Number of egg and meat-type breeding flocks in plan.....	3,831	3,860	3,831
Number of water fowl, exhibition poultry, and game bird breeding flocks in plan.....	4,443	4,443	4,443
Number of States classified as U.S. Mycoplasma Gallisepticum Clean (turkeys).....	12	13	12
Turkey breeding flocks in the plan.....	681	690	681
Number of garbage inspections.....	40,000	39,500	39,000
Number of violations of the SHP Act.....	575	515	500
Searches for unlicensed garbage feeders.....	76,582	75,817	75,000
Exotic diseases and parasites:			
Investigations of suspicious cases.....	299	300	300
Exotic Newcastle disease (VND) outbreaks.....	—	—	—
Compliance:			
Inspections conducted at livestock markets and at other concentration points.....	13,859	15,337	15,337
Inspections conducted at slaughter establishments.....	3,580	4,855	4,855
Animal and plant health regulatory enforcement:			
Agricultural quarantine inspection:			
Field investigations.....	339	350	400
Formal cases.....	980	1,000	1,000
Warning notices.....	46	50	50
Stipulations.....	544	550	600
Cases sent to OGC.....	190	200	200
Animal health monitoring and surveillance:			
Field investigations.....	1,432	1,400	1,200
Formal cases.....	762	750	700
Warning notices.....	296	271	250
Stipulations.....	44	60	75
Cases sent to OGC.....	66	65	60
Animal welfare:			
Field investigations.....	672	700	750
Formal cases.....	921	925	950
Warning notices.....	597	600	600
Stipulations.....	141	150	150
Cases sent to OGC.....	69	75	75
Horse protection:			
Field investigations.....	87	50	50
Formal cases.....	26	20	20
Warning notices.....	—	—	—
Stipulations.....	—	—	—
Cases sent to OGC.....	18	20	20
Veterinary biologics:			
Field investigations.....	25	25	25
Formal cases.....	8	10	10
Warning notices.....	1	5	5
Stipulations.....	—	—	—
Cases sent to OGC.....	—	2	5

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Program	1993 Actual	1994 Estimated	1995 Estimated
Fruit fly detection:			
Traps set:			
Mediterranean	41,000	42,500	42,600
Melon	13,500	13,900	13,900
Oriental	20,200	20,800	20,800
Mexican	18,700	19,500	20,300
Total	93,400	96,700	97,600
Plant pest detection:			
Special area wide pest reporting projects	10	6	4
Pest maps developed	1,000	1,000	1,000
Biocontrol projects supported	5	5	6
Exotic species surveyed	20	20	20
Species distributions recorded	10	10	10

3. Pest and disease management programs -- In cooperation with the States, APHIS conducts programs to detect, prevent, and eradicate pests and diseases which are harmful to agriculture. The Agency monitors and regulates interstate shipments of plants, livestock, and related materials to prevent the spread of disease and the distribution of impure, unsafe, and nonefficacious materials and products. Through the Animal Damage Control program, APHIS protects agriculture from detrimental animal predators through identification, demonstration, and application of the most appropriate methods of control.

The statutory authority for this work is contained in 7 U.S.C. 2.17, 2.51, 7-7b, 8, 11, 15, 17, 30, 54, 55, 371.2, 429, and 3801-3813; 15 U.S.C. 44; 19 U.S.C. 4; 21 U.S.C. 4, 5, and 45, 111, 114, 117, 120, 122-126, 130, 134; 46 U.S.C. 15; and 49 U.S.C. 20. Principal legislative authority for these activities is contained in the Animal Industry Act of May 29, 1884; Act of August 30, 1890; Act of February 2, 1903; Act of 1903, Act of March 3, 1905; Tariff Act of June 17, 1930; the Animal Damage Control Act of 1931; Act of September 21, 1944; Organic Act of 1944, as amended by P.L. 94-231, enacted March 15, 1976; Act of February 28, 1947; Act of September 6, 1961; Act of July 2, 1962; P.L. 92-629 of January 3, 1975; the Swine Health Protection Act of October 17, 1980; Public Law 97-46 of September 25, 1981; Act of October 14, 1982; Act of January 13, 1983; P.L. 99-198 of December 23, 1985; and the Food, Agriculture, Conservation, and Trade Act (Farm Bill) of 1990. The activities carried out are as follows:

- Animal Damage Control (ADC) - The ADC program was established in 1885 as the Bureau of Biological Survey under the U.S. Department of Agriculture (USDA). In 1939, the program was transferred to the U.S. Department of the Interior, Fish and Wildlife Service. Pursuant to P.L. 99-190; H.J. Res. 465, 99 Cong. 1st Sess. FY 1985, ADC was transferred back to USDA and is now administered by APHIS. The goal of the ADC program is to help solve problems that are created when species of wildlife cause damage to agricultural, industrial, or natural resources; or present a threat to public health and safety. Under the authority of the Animal Damage Control Act, the program conducts research and carries out cooperative activities with other Federal, State or local agencies, organizations, or private individuals. The program helps protect agricultural and natural resources, property, or endangered species and prevents wildlife hazards at airports or other locations where there is a need to safeguard public health.
- Aquaculture - The proposed program's goal is to assist the aquaculture industry in controlling aquatic diseases and pests and to facilitate commerce. Aquaculture is currently the most rapidly growing segment of agriculture. Depredation from large bird populations damage the aquaculture industry's attempt to create a viable and economically sound industry.

The initial activities would include providing technical assistance to producers, developing a cooperatively funded program for operational assistance to producers, coordinating depredation permits with the Fish and Wildlife Service and the State wildlife agencies, working with the Fish and Wildlife Service and the State Wildlife agencies to develop bird damage management plans, establishing liaison with wild fishery interests, and evaluating current control efforts with a view toward development of improved control methods in the future.

- Biocontrol - This program's goal is to implement biological control programs using parasitoids, predators, and pathogens to control agricultural pests of economic importance in a cooperative effort with Federal and State agencies. The program carries out the importation, quarantine screening, rearing, release, and evaluation of beneficial organisms to control pests of economic importance. Biological control is an alternative to using traditional chemicals for controlling plant pests. Public environmental concerns such as water and air quality, the potential carcinogenic effects of certain pesticides, and increasing pest resistance to pesticides have made it imperative for APHIS to continue to develop and improve upon biological control methods. APHIS works with international organizations and other Federal agencies, the States, and universities in conducting a number of biological control projects including leafy spurge, diffuse and spotted knapweed, Colorado potato beetle, Russian wheat aphid, Sweet potato whitefly, Euonymus scale, Cereal leaf beetle, and the Brown citrus aphid.
- Boll weevil - The boll weevil program consists of two regional eradication programs and one containment program. These programs are cooperative efforts, of which APHIS pays 30 percent of program costs and cooperators pay 70 percent.
- High Plains Control - This program was established in 1963 to contain the spread of the boll weevil and prevent it from infesting over 4 million acres of cotton in west Texas and New Mexico.
- Southeast Eradication - The program has eradicated the boll weevil from Virginia, North Carolina, South Carolina, Georgia, and Florida, and portions of southern Alabama. Post-eradication activities continue in these areas to prevent reinfestation. In response to grower interest, APHIS plans to expand the eradication program into the remaining areas of Alabama, eastern Mississippi, and southern Tennessee. The program calls for eradication of the boll weevil from all cotton growing areas of the United States by the year 2015.
- Southwest Eradication - The program has eradicated the boll weevil from Arizona, southern California, and northwestern Mexico. Two areas in northern Mexico, Sonora and Caborca, are currently under treatment. Eradication in northern Mexico should be confirmed within the next 3 years, reducing the risk of reinfestation in Arizona.
- Brucellosis - The objective of the State-Federal Cooperative Brucellosis Program is to eradicate Brucella abortus from the bovine population and Brucella suis from the swine population of the United States.

For the last 4 years, the bovine program has operated under the industry supported Rapid Completion Plan (RCP). This plan would eliminate brucellosis from the United States by the end of FY 1998 at the current funding level. The RCP places particular emphasis on the depopulation or whole herd vaccination of affected herds and on close adherence to all provisions of the Brucellosis Uniform Methods and

Rules. Major program tools include calfhood vaccination, data management, and the elimination of infection from herds by depopulation.

Program plans in FY 1994 include qualifying the remaining Class B State, Texas, for advancement to Class A status, and qualifying four Class A States, California, Tennessee, Alabama, and Iowa, to Class Free status.

- Cattle Ticks - The cattle tick program is a cooperative Federal-State-industry effort to prevent the re-establishment of the cattle fever tick, Boophilus annulatus and B. microplus in the United States; to maintain a permanent buffer zone along the Texas-Mexico border; and to eradicate the tropical bont tick, Amblyomma variegatum and the cattle fever tick, B. microplus, from Puerto Rico and the U.S. Virgin Islands.

In the continental United States, the program is concentrated along the Texas-Mexico border, where the Rio Grande river serves as a natural barrier. Animal health inspectors conduct systematic patrols and inspections on horseback, in the permanent quarantine zone along the border. In addition, all livestock crossing the border and entering or leaving the quarantine zone are examined and treated for ticks to eliminate the risk of cattle ticks becoming established in the United States.

The Puerto Rico program involves the systematic treatment of all tick-infested premises with an acaricide. After the treatment regimen is completed, livestock on the premises are inspected for ticks to ensure that they remain tick-free.

Program objectives for FY 1994 include maintaining a quarantine zone, systematic patrols, and inspections along the Texas-Mexico border; and continuing the tick eradication program in Puerto Rico.

- Golden Nematode - The program regulates golden nematode infested crops in the State of New York and prevents the spread of the nematode to other potato producing States. To accomplish its goal, APHIS cooperates with the New York State Department of Agriculture, the Agricultural Research Service, the Extension Service, Cornell University, and the New York Seed Improvement Cooperative. The program enforces regulations and sanitary requirements, supports research to develop new resistant potato varieties, and encourages grower acceptance of existing resistant varieties.
- Grasshopper and Mormon cricket - Preventing grasshoppers and Mormon crickets from causing significant damage to U.S. rangeland and cropland is this program's goal. APHIS accomplishes this goal by conducting surveys to determine the extent of grasshopper and Mormon cricket populations and by conducting control activities on Federal, State, and privately owned rangeland. A limited amount of cropland may be included in a control program, when it is contained within a block of rangeland. Control activities include both pesticide application and the introduction of biological control agents. A no-year fund was established in 1986 to finance control activities on rangeland and cropland. A supplemental appropriation was made in FY 1990 to fund control activities on land in the conservation reserve program (CRP).

APHIS began a grasshopper Integrated Pest Management (IPM) project in FY 1987. The project was designed to find long-term environmentally acceptable solutions to grasshopper infestations. The transfer of the technology to field activities is continuing.

- Gypsy moth - The goal of the gypsy moth program is to prevent the artificial spread of the pest from the generally infested area. The currently infested area includes all or part of 15 eastern States, ranging from Maine to North Carolina, and west to Michigan. The program's main functions are regulatory, survey, and control activities. Regulatory activities conducted within the generally infested area include the inspection, treatment, and certification of regulated articles for movement to non-infested areas. Survey activities are conducted in cooperation with the States to detect and delimit any isolated pest populations outside of the generally infested area. Control activities are conducted in cooperation with the States and the Forest Service to eliminate identified isolated infestations. APHIS is responsible for all infestations not exceeding 640 acres that occur on State or private land.
- Honey bee pests - The program's objectives are to promote techniques that prevent Africanization of managed European honey bee colonies, prevent the introduction of new exotic honey bee pests, and assist the States with monitoring the migration of the Africanized honey bee (AHB). Because the AHB is more defensive and less productive than European bees, it poses the most immediate danger to the beekeeping industry. During 1990, Africanized honey bees initially migrated from Mexico to south Texas. In cooperation with the States and the beekeeping industry, APHIS monitors swarm trap lines in southern States to track the movement of AHB. The Agency supports the national honey bee certification plan developed by the National Association of State Departments of Agriculture (NASDA), which requires certification that honey bees are free from the AHB strain. In addition, the Agency has a representative on the AHB Technical Working Group. APHIS also operates the National Agricultural Pest Information System (NAPIS) data base to maintain AHB survey records, operates AHB traps at ports of entry, assists the States in setting up identification laboratories, loans identification lenses for the laboratories, and supplies traps and lures to States through cooperative agreements.
- Imported fire ant (IFA) - The IFA program is established to control existing infestations and reduce further spread of IFA. Since its introduction into the United States in 1918, IFA has spread to 11 Southern States and Puerto Rico. In the late 1950's, the Department began working with the infested States to control IFA. At that time, the Department imposed a Federal quarantine and developed a cooperative control program designed to limit the ant's spread. When surveys indicate that IFA have been intercepted, new counties are included in IFA regulatory maps which are distributed to the State regulatory officials. Currently, APHIS is cooperating with the University of Arkansas to develop methods and demonstration projects for imported fire ant control. APHIS also cooperates with infested States to prevent further spread by regulating certain articles like nursery stock and soil moving equipment. APHIS works with the Agricultural Research Service to screen and develop promising new chemicals and biocontrol agents.
- Miscellaneous plant diseases - APHIS responds to numerous reports of new plant pest species in the United States each year. The miscellaneous plant pest program provides the mechanisms for response to those pests not covered under a specific line-item. Program activities include delimiting surveys, control or eradication treatments, and restricting the movement of commodities which could spread the pest. In the international arena, APHIS facilitates surveys for several agricultural pests by offering technical advice to countries throughout the Caribbean, Central America, and Mexico.

- Noxious Weeds - APHIS' responsibilities under the Federal Noxious Weeds Act of 1974, are to prevent the entry of noxious weeds into the United States from foreign countries, detect and delimit infestations of those weeds that are already in the United States, and to eradicate infestations where feasible. The noxious weeds program is performed in cooperation with State and local agencies. Program methods include port-of-entry inspections, surveys to determine the scope of infestations, eradication feasibility studies, and other control and eradication projects. The program has conducted survey and eradication feasibility studies on crupina in Idaho, goatsrue in Utah, itchgrass in Louisiana, and hydrilla in California. In recent years control efforts have been directed at common crupina, goatsrue, hydrilla, Salsola vermiculata, Orobanche ramosa, Orobanche minor, and Cuscuta japonica.
- Pink bollworm - APHIS works with State agencies, grower organizations, and cotton producers to prevent pink bollworm from spreading to non-infested areas. The pink bollworm is a serious pest of cotton, but can reproduce on several other plant species in the United States. The pest is fairly widespread in the Cotton Belt from southern California through Texas, with limited areas of infestation occurring in Arkansas and Louisiana. In recent years, moths have been caught in Mississippi, Missouri, and Tennessee. Program activities include quarantine enforcement, trapping, methods development, and operation of a sterile-moth rearing facility. Pink bollworm moths are raised, sterilized, and released in the San Joaquin Valley, California, to mate with native moths that fly in from infested areas in the south. This sterile union prevents the infestation of over 1 million acres of cotton across the valley.
- Pre-Harvest Pathogen Reduction - APHIS will assist in providing the United States with a safer and more wholesome animal food product through optimum food safety and animal health. This goal will be accomplished by improving animal health on the farm and reducing the risk of foodborne pathogens of animal origin from reaching the general public. By achieving a higher food safety standard in this country, U.S. producers will have a definite advantage in securing competitive international markets.
- Pseudorabies - APHIS participates in a cooperative Federal-State-Industry program to eradicate pseudorabies. This herpes virus causes severe economic losses in swine due to reproductive problems including abortion, stillbirth, death in newborn pigs, pneumonia in pigs raised for market, and fatality in all other domestic livestock. The program began in January 1989 and will require an estimated 10 years to complete. APHIS provides national program coordination, technical advice, data management, and public information.

The pseudorabies eradication program has been an ideal model of producer and government teamwork. The program guidelines are called the Pseudorabies Program Standards and were developed by APHIS, State, and industry leaders. Program participation requires the formation of a State pseudorabies committee, which consists of swine producers, animal scientists, veterinarians, State and Federal regulatory officials, and other swine industry representatives. Participation also requires incorporating the standards into the State's regulations. The educational efforts employed to eradicate pseudorabies have improved the overall herd health management of swine farms. Pseudorabies-free high-health status swine are more profitable for swine producers. Animals or pork products from such farms are more acceptable to meat processors and growing international markets.

All 50 States, Puerto Rico, and the Virgin Islands participate in and receive Federal funds for this industry-initiated program. Program progress is measured by advancement through five stages, with Stage I being the initial stage and Stage V being the final stage. Entry into Stage V requires having no infected herds and testing 10 percent of the breeding swine in the State annually for the previous 2 years. Once Stage V is achieved, the surveillance can be reduced to five percent of the State's breeding swine, thereby reducing program costs. To qualify for Stage IV status, a State must have no known pseudorabies infection. Mandatory cleanup of infected herds is required to qualify for Stage III. This may involve a combination of depopulation, vaccination, test and removal of reactor animals, and offspring separation. Before entering Stage III, a State must also have one percent or less of its swine herds infected with pseudorabies. Stage II is the control phase in which significant progress must be made to reduce the number of infected herds to one percent or less. In addition, any swine herds within a 1.5 mile radius of an infected herd must be monitored and epidemiological tracing of swine movements to and from infected herds must be done. Stage I requires that the State pseudorabies committee formulate plans for a reliable determination of prevalence and seek the regulatory/legislative authority to conduct an effective control/eradication program.

- Salmonella enteritidis (SE) - SE continues to be an important poultry disease and a serious public health concern. In recent years, it has been found in a considerable number of domestic commercial egg-laying chicken flocks and has contaminated commercial table eggs, causing human illness and deaths. The primary goal of the SE traceback program is to reduce the spread of the disease as well as the human illnesses and deaths caused by egg-related SE. Since the program began in 1990, 248 SE outbreaks in humans have been reported, involving at least 7,716 cases and 12 deaths. Of this total, 78 were egg-related. Tracebacks from these outbreaks led to 34 different egg-layer flocks, including some of the largest in the United States. These flocks were located in the following States: 17 in Pennsylvania, 4 in Indiana, 2 in Maryland, 2 in New York, and 1 each in Colorado, Delaware, New Jersey, Kansas, Minnesota, Texas, Alaska, Vermont, and Michigan. As of January 1, 1994, only one of these flocks is still under restriction; this flock is in Indiana. The remaining flocks have either been released from restriction or depopulated. Eggs from the positive flocks were prevented from being sold interstate as table eggs, and instead were sent to pasteurization plants. Approximately 7 million laying hens were involved and approximately 2.150 billion eggs have been kept off the table egg market.

APHIS will continue the traceback program in FY 1994. In addition, the Agency is conducting a large pilot program in Pennsylvania to better determine how to prevent and control SE in poultry flocks. The program has monitored or is now monitoring 125 flocks with a total population of 7.5 million laying hens. As a direct result of the Pilot Project, APHIS has begun an Egg Quality Assurance program, which should cover approximately 15 million egg layers in that State.

There are also many efforts by other agencies and groups to lower SE incidence. Egg producers have adopted a wide range of measures to reduce the risk of infecting their flocks and contaminating eggs with SE. In FY 1990, the Food and Drug Administration added eggs to the "hazardous foods" list and recommended a 45 degree F. refrigeration requirement and the use of pasteurized eggs in institutions. The egg industry is recommending more stringent refrigeration requirements for eggs throughout the production process. Through the combined efforts of APHIS, egg producers, restaurants, consumers, industry

representatives and other government agencies, it should be possible to decrease SE outbreaks to 25 per year by the year 2000, from the current annual level of approximately 60.

- Scrapie - The goal of the scrapie program is to reduce the incidence and control the spread of scrapie, a transmissible disease of sheep and goats that causes a slowly progressive degeneration of the central nervous system. This disease is always fatal and no diagnostic test is available to identify affected animals before death. To reduce the incidence and control the spread of scrapie, APHIS established a voluntary scrapie flock certification program (VSFCP) in FY 1993 which calls for the gradual development of flocks that are certified to be free of scrapie. Participating flocks progress through four classes over time, with each class representing a lower risk that the flock is infected with scrapie. A flock must spend a minimum amount of time in a given class, and each class has specific requirements for flock record-keeping, new animal purchases, animal identification, actions upon animal deaths, and submission of diagnostic samples. The program was developed through the process of negotiated rulemaking, which was a cooperative effort involving producers, accredited veterinarians, allied industry representatives, State animal health officials, and APHIS. In FY 1994, APHIS will continue to conduct activities associated with the VSFCP and will intensify efforts to encourage producer participation. The Agency also continues to support cooperative research to develop a live animal diagnostic test and to determine if embryo transfer is effective in preventing scrapie transmission.
- Tropical Bont Tick (TBT) - The new TBT program will be a cooperative effort with the Food and Agriculture Organization of the United Nations (FAO) European Community, Caribbean governments, and other participants such as APHIS. The objective of the program is to eradicate the TBT from the Caribbean where it is currently established on 14 islands and reported from 19, before it can spread to mainland areas including Venezuela, Florida, and the Yucatan Peninsula. As the program progresses, APHIS will collaborate with the Food and Agriculture Organization of the United Nations, the Inter-American Institute for Cooperation on Agriculture, and the Economic Community of Caribbean countries, as part of regional efforts aimed at controlling the spread of the tick and eradicating it from selected islands.

The TBT is a vector of a causative agent of heartwater disease in ruminants and is also associated with increased incidence of bacterial skin infections which can lead to other infections and diseases. The spread of TBT throughout its potential range in the Western Hemisphere would most severely affect dairy farms, costing producers up to \$762 million annually. TBT has a low probability of reintroduction into the Caribbean region once it is eradicated, and eradication of the TBT while it is restricted to this area would provide the greatest level of security to the rest of the Americas.
- Tuberculosis - The goal of this program is the eradication of bovine tuberculosis (TB) from the United States. Primary program tools include the traceback and testing of cattle herds from which infected animals were identified at slaughter, testing of suspect cattle to identify positive cases, and full epidemiological investigation to identify sources of infection and possible exposure to other herds. Sources of infection and exposure can be cattle, bison, elk, deer, and other warm-blooded mammals. Restrictions are placed on the interstate movement of cattle that are reactors, exposed, or suspects. Limited indemnities are provided to owners of TB-infected animals destroyed in connection with the program.

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During FY 1994, the Agency, with the cooperation of FSIS, plans to further increase the rate of submissions of TB-like lesions found during inspections at slaughter. A greater submission rate would aid in the goal of locating new herd tracebacks. Uniform Methods and Rules will go into effect for TB in deer and elk to include using slaughter surveillance methods to identify TB in deer and elk herds. The Agency will explore ways to reduce the importation of Mexican steers with TB into the United States through improved communication with Mexico regarding the control and eradication of TB in animals undergoing international movement.

- Witchweed - The program's goal is to prevent the spread of witchweed to host crop producing areas of North Carolina and South Carolina and move towards eventual eradication of this pest. The current levels of infestation will allow APHIS to transfer the eradication responsibilities to the States by FY 1995. Afterwards, the Agency involvement will be limited to providing financial and technological support to the States. This will allow the States to conduct post-eradication surveys and spot-treat new infestations when detected. If allowed to spread into the corn belt, witchweed would cause an estimated 10-percent yield loss of the \$20 billion corn, sorghum, and sugarcane industries in the United States.

The levels of pest and disease management activities are shown by the selected examples that follow:

Program	1993 Actual	1994 Estimated	1995 Estimated
ADC Operations:			
Number of livestock protected:			
Sheep and goats.....	8,517,100	8,600,000	8,400,000
Cattle.....	11,491,000	11,500,000	11,450,000
Crop acres protected:			
Small grains.....	1,380,000	1,400,000	1,350,000
Sunflowers.....	325,000	335,500	340,000
Fruit and nut orchards.....	179,000	178,000	179,000
Hay, alfalfa, and pasture.....	490,000	495,000	500,000
Citrus.....	47,500	48,000	49,000
Corn.....	157,500	159,000	160,000
Soybeans.....	19,500	21,500	22,500
Vineyards.....	140,000	142,000	145,000
Range and forest acres protected:			
Range.....	8,120,000	8,500,000	8,000,000
Forest.....	3,150,000	3,250,000	3,100,000
Health and safety accomplishments:			
Airports (prevent bird strikes).....	380	385	375
Rabies projects.....	70	72	65
Plague surveillance projects.....	270	270	260
Number of requests for assistance:			
Agriculture.....	109,100	110,000	111,000
Urban interests.....	87,500	90,000	92,000
Human health and safety.....	21,700	22,000	22,500
Industrial facilities.....	1,432	1,500	1,500
Natural resources.....	1,225	1,280	1,285
Biological Control:			
Natural enemies released (thousands):			
European corn borer.....	1,200	-	-
Colorado potato beetle.....	670	1,500	3,000
Diffuse and spotted knapweed.....	76	90	68
Leafy spurge.....	275	300	400
Russian wheat aphid.....	3,000	2,700	2,500
Sweetpotato whitefly.....	3,466	10,000	10,000
Euonymus scale.....	36	60	75
Cereal leaf beetle.....	24	35	50

Program	1993 Actual	1994 Estimated	1995 Estimated
Boll Weevil:			
Weevil-free acres (thousands):			
High Plains.....	2,500	2,500	2,500
SE eradication.....	430	1,010	1,100
SW eradication.....	1,250	1,650	1,650
Acres under treatment (thousands):			
High Plains.....	-	-	500
SE Eradication.....	580	410	934
SW Eradication.....	400	25	25
Brucellosis:			
Cattle:			
Class Free status States*.....	35	39	43
Class A status States.....	17	14	10
Class B status States.....	1	-	-
Total number of quarantined herds at the end-of-fiscal year.....	283	212	159
* Includes Puerto Rico, U.S. Virgin Islands, and D.C.			
Cattle ticks:			
Infested premises under treatment outside of quarantine zone at end of FY (Texas).....	3	4	4
Infested premises under treatment inside quarantine zone at end of FY (Texas).....	7	9	16
Premises freed of ticks (cumulative) Puerto Rico (bovine only).....	12,015	14,000	16,000
Grasshopper and Mormon cricket:			
Cumulative acres treated (thousands).....	85	1,000	2,000
Acres treated in CRP lands (thousands).....	1	1	1
Economically infested acres from survey (thousands).....	24,766	15,944	28,000
Gypsy moth:			
Acres treated (funded through contingency funds).....	51,037	50,000	50,000
Honeybee pests:			
Swarm traps at ports-of-entry.....	1,442	1,442	1,500*
Swarm traps operated by APHIS in monitoring spread of Africanized honeybee.....	1,480	-	-
* Funded through miscellaneous plant pests in FY 1995.			
Imported fire ant:			
Regulatory violations (State and Federal).....	34	40	-
Regulatory inspections (State and Federal).....	28,000	25,000	-
Noxious weed program:			
Acres treated for common cupress in Oregon.....	2,000	2,000	2,000
Acres treated for common cupress in Washington.....	480	480	480
Acres treated for goatsrue in Utah.....	39,000	39,000	39,000
Acres treated for <i>Orobanche ramosa</i>	390	350	335
Pink bollworm:			
Sterile insects reared (millions).....	834	1,222	1,222
Sterile moths released (millions):			
San Joaquin Valley.....	834	800	800
Imperial/Coachella Valley (demonstration project).....	-	422	422

Program	1993 Actual	1994 Estimated	1995 Estimated
Pseudorabies:			
States enrolled in the National Pseudorabies Eradication Program:			
Stage I States.....	4	—	—
Stage II States.....	9	3	6
Stage II/III States.....	5	5	5
Stage III States.....	19	19	15
Stage IV States.....	6	10	25
Stage V States.....	9	15	4,000
Known infected herds.....	6,600	5,500	700,000
Market/Slaughter samples tested.....	600,000	650,000	20
States that advanced to next stage.....	17	18	300,000
Hogs infected during the year.....	989,875	600,000	1,000,000
Hogs currently infected.....	3,843,830	2,500,000	800
Herds infected during the year.....	1,740	1,200	4,000
Herds currently infected.....	6,754	5,500	3,000
Herds cleaned up during the year.....	2,796	3,000	4,000
Herds on clean-up plans.....	6,091	5,500	
Salmonella enteritidis:			
Flocks enrolled in voluntary SE control program...	60	125	250
States that have adopted voluntary SE control programs.....	3	3	5
Human SE outbreaks per year.....	57	40	20
Number of these cases that were egg-related.....	18	12	10
Human SE cases per year resulting from outbreaks.....	2,500	2,000	1,500
Egg-layer flocks implicated in the outbreaks.....	3	2	2
Egg-layer flocks under restriction at end-of-year.....	1	1	1
Scrapie:			
Total number of infected flocks, includes new and existing.....	139	85	85
Number of new infected flocks found.....	110	55	55
Number of source flocks.....	8	10	10
Flocks participating in flock certification program...	28	60	150
Flocks eligible to advance to higher certification levels.....	—	28	32
Flocks that advanced to higher certification levels.....	—	28	32
Flocks in Class C (1st year).....	28	32	90
Flocks in Class B (2nd year).....	—	28	60
Flocks in Class A (2nd year).....	—	—	—
Flocks certified.....	—	—	—
Tuberculosis:			
States accredited-free status.....	42	43	44
States modified-accredited status.....	10	9	8
Herds located.....	3	8	8
Herds depopulated.....	2	6	6
Witchweed:			
Acres infested at end-of-year.....	38,000	25,600	15,000
Acres released from quarantine.....	10,000	12,400	10,600
Acres previously released from quarantine.....	387,600	397,600	410,000

4. Animal care programs -- APHIS is mandated by Congress to enforce the Animal Welfare Act (AWA) of 1966 and the Horse Protection Act (HPA) of 1970. The statutory authority for this work is contained in the respective Acts and the corresponding amendments. The program activities contain the following principles:

-- Animal Welfare - Under the Animal Welfare Act (AWA), APHIS is responsible for developing regulations implementing its provisions and ensuring compliance with these regulations by the regulated entities.

The AWA stipulates that warm-blooded animals utilized for research or exhibition, or raised for the wholesale pet trade, receive humane care, treatment, and handling. The transportation of regulated animals in commerce is also covered by the AWA. To prevent the utilization of stolen pets for research purposes the AWA requires that records of acquisition and disposition be maintained for dogs and cats raised or utilized under the AWA. The activities of the program are accomplished via a licensing and/or registration requirement combined with an inspection process. To ensure compliance, APHIS is required by law to conduct annual inspections of all research facilities and reinspect noncompliant areas until these areas achieve compliance.

With the enactment of an amendment to the AWA that called for a certification to accompany random-source dogs and cats sold to dealers by humane shelters, certain pounds, and research facilities, APHIS published final regulations on July 22, 1993, which addressed the requirements. The amendment requires that regulated facilities comply with holding periods. This legislation was passed by Congress to prohibit the use of stolen pets in research and to provide owners the opportunity to locate their animals. The final rule became effective August 23, 1993.

As a result of an Office of the Inspector General review, APHIS implemented action for the improved welfare of dogs in the pet industry. This includes changes in policy, management, enforcement, the control of unlicensed dealers, and other areas for a better enforcement of the animal welfare standards. APHIS also recommended legislative changes to strengthen and improve its authority with regard to stolen dogs.

-- Horse Protection - The Department is committed to the elimination of the inhumane practice of soring horses. The Horse Protection Act (HPA) prohibits showing, selling, transporting, or exhibiting sored horses. Soring is inflicted through the use of action devices, chemicals, or a combination thereof applied to a horse's lower (pastern) limbs in order to accentuate an unnaturally high stepping gait.

The Department certifies horse industry organizations that meet regulatory criteria to inspect horses at shows, sales, auctions, and exhibitions. APHIS monitors compliance of the program by making unannounced inspections and evaluating the Designated Qualified Persons (DQP's) that inspect horses on behalf of the certified organizations.

During FY 1993, APHIS emphasized cooperative enforcement techniques and communication with various horse industry organizations. In FY 1994, APHIS intends to strengthen its professional relationships with industry inspectors and provide continuing educational support.

The levels of animal care activities are shown by the selected examples that follow:

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Program	1993 Actual	1994 Estimated	1995 Estimated
Animal welfare:			
Complaints investigated and resolved.....	689	647	711
Number of inspections conducted at licensees and/or registrants.....	19,861	15,790	17,470
Number of violations processed.....	980	433	459
Dealer inspections.....	6,280	7,000	7,200
Research inspections.....	4,355	4,500	4,650
Exhibitor inspections.....	2,944	2,750	2,900
Intransit inspections			
Carners.....	2,368	2,149	2,278
Handlers.....	386	351	372
Number of searches conducted.....	2,983	3,200	3,425
Preliminary inspections.....	2,213	2,200	2,200
Horse protection:			
APHIS staff days and/or nights of inspecting or monitoring horse shows and sales.....	200	180	180

5. Scientific and technical services -- APHIS develops methods to control animals and pests that are detrimental to agriculture, wildlife, and public safety. The Agency's regulatory structure brings the benefits of genetic research to the marketplace, while protecting against the release of potentially harmful organisms into the environment. APHIS also conducts diagnostic laboratory activities that support the Agency's veterinary disease prevention, detection, control, and eradication programs. The Agency also provides and directs technology development in coordination with other groups in APHIS to support plant protection programs of the Agency and its cooperators at the State, national, and international levels.

The statutory authority supporting this work is contained in 7 U.S.C. 7-7b, 8, 11, 15, 17, 30, 54, 55, 429, and 3801; 15 U.S.C. 44; 19 U.S.C. 4; 21 U.S.C. 4, 5, and 45; 46 U.S.C. 15; and 49 U.S.C. 20. The principal legislative authority for these activities is contained in the Act of May 29, 1884; Act of August 30, 1890; Act of February 2, 1903; Act of March 3, 1905; Tariff Act of June 17, 1930; Act of September 21, 1944; the Organic Act of 1944, as amended by P.L. 94-231, enacted March 15, 1976; Act of February 28, 1947; Act of September 6, 1961; Act of July 2, 1962; the Virus-Serum-Toxin Act of March 14, 1913; and the ADC Act of 1931. Authority to collect user fees for veterinary diagnostics is contained in Section 2509 of the Food, Agriculture, Conservation, and Trade Act (Farm Bill) of 1990.

- ADC Methods Development - The ADC program was transferred to APHIS on December 23, 1985, pursuant to P.L. 99-190; H.J. Res. 465, 99 Cong. 1st Sess. 1985. From 1939 until its transfer to APHIS, the program was a part of the U.S. Department of the Interior's Fish and Wildlife Service. The basic program mission is to protect American agriculture and other resources through identification, demonstration, and application of the best methods of controlling wild and free ranging animals that are detrimental to agriculture, other wildlife, and public safety. In support of this mission, research and development of control techniques and devices for the operations program and APHIS clientele are provided by the Denver Wildlife Research Center. The center conducts research to maintain current pesticide registrations with the Environmental Protection Agency for products such as strychnine, Compound 1080, and Starlicide (DRC-1339). Also, new or improved control tools such as soft traps, the livestock protection collar, repellents, and electroshock techniques are researched.
- Biotechnology/Environmental Protection - This program's goal is twofold: (1) to protect American agriculture while allowing for the development of significant biotechnologically derived products for the

benefit of the agricultural producers and consumers, and (2) to assure that APHIS is in full compliance with the National Environmental Policy Act and other applicable statutes, executive orders, and regulations in all of its programs.

The biotechnology component of the program regulates the field release, interstate movement, and importation of genetically modified organisms, and licenses recombinant derived veterinary biologics for sale and distribution in the United States. The intent of this program is to certify and ensure that the introduction and field testing of new products do not present potential risks to America's plant and animal resources and/or industries, the general public, or the environment. The program provides the added benefit of fostering technology transfer by allowing for the safe field testing of potentially beneficial plants and micro-organisms and licensure of recombinant-derived veterinary biologics. Also, the program enhances technology transfer by working to reduce domestic and international barriers to biotechnology development and trade. Both activities support the President's goal of maintaining America's competitive edge in biotechnology.

APHIS uses environmental and scientific staff, and the National Monitoring and Residue Analysis Laboratory (NMRAL) at Gulfport, Mississippi to carry out a "circle of environmental protection" concept that enables APHIS' operational programs to comply in a proactive fashion with all environmental requirements--the National Environmental Policy Act and other environmental laws, regulations, and Executive Orders. Environmental scientists work with program planners to identify and develop viable alternatives to current control and eradication programs and to document APHIS' environmental planning activities.

The NMRAL provides analytical chemical services in support of APHIS' cooperative treatment programs employing agrochemicals to control or eradicate plant and animal pests. Principal programs supported include agricultural quarantine inspection, grasshopper, imported fire ant, boll weevil, Mediterranean fruit fly, and gypsy moth. In addition, the laboratory's activities are important to the Department by helping to promote food safety through the testing of various food products for pesticide residues, work which NMRAL typically performs under contract with the requesting agency. The program also maintains the registration of chemicals and other substances used in current APHIS programs, while helping to identify emerging, less environmentally invasive alternatives to current practices. In addition, the program develops monitoring plans that are used to assess the impact of Agency actions on the environment, and analyzes samples of soil, water, and crops for pesticide residue to determine the safety of ongoing and alternative programs.

- Integrated Systems Acquisition Project (ISAP) - ISAP is an Agency initiative to establish a mechanism to procure automated data processing (ADP) equipment, software, and services which will enable APHIS' many information management applications to be developed and operate in a consistent, common ADP environment. This procurement is designed to replace the Agency's current mixture of incompatible, ADP systems. The ISAP initiative will improve the delivery and administration of Agency programs by integrating technologies and information across all levels of the Agency.
- Plant methods development laboratories - Methods development supports APHIS programs primarily by optimizing existing pest control practices and by developing new technologies for pest exclusion, detection, and control. This is accomplished by evaluating new biological and

chemical materials, adapting or inventing equipment, providing technical consultation and training, collecting and disseminating pertinent information, participating in strategic and tactical planning, serving as a liaison between APHIS and the research community, and introducing technological advancements into integrated pest management systems.

- Veterinary biologics The goal of this program is to prevent the importation, production, and distribution of impure, ineffective, unsafe, or impotent veterinary biological products in the United States. Program activities include the licensing of veterinary biological products, inspection of licensed manufacturing facilities, testing of statistically based samplings of licensed products, and the issuance of permits for the importation of these products. The program regulates both the interstate and intrastate distribution and sale of veterinary biological products. These activities help protect America's multi-billion dollar livestock and pet industries. The program also helps ensure that industry has an efficient regulatory pathway to bring beneficial products to American agriculture. This function fosters the growth of America's veterinary biologics industry, which is making use of the explosive growth of microbiological processes to develop sophisticated new products. Finally, the program participates in efforts to reduce unfair regulatory barriers to the entry of American veterinary biological products into foreign markets and works with industry to reduce the use of laboratory animals by making greater use of *in vitro* testing.

- Veterinary diagnostics - APHIS maintains a diagnostic program for foreign and domestic animal diseases that threaten the livestock, poultry, and related industries of the United States. The program consists of diagnostic laboratory activities which include diagnostic assistance to the livestock and poultry industries, as well as to the States. APHIS operates laboratories located at Ames, Iowa, for diagnosing domestic diseases, and Plum Island, New York, for work on diseases exotic to the United States such as FMD. Services include differential diagnosis, blood and tissue examination, culture analysis, toxicological testing, and reagent and reference antigen production. The program also provides training in domestic and FAD diagnosis.

User fees were implemented in late FY 1993 to cover direct labor and material costs for veterinary diagnostic testing, reagent production, and reference assistance testing performed for private entities. During FY 1994, the user fee schedule will be reviewed to reflect current costs and to add tests, reagents, and services.

The Agency will increase its activity in the area of preharvest food safety by reviewing diagnostic procedures for blood borne pathogens and providing diagnostic assistance for APHIS's food safety initiatives.

The levels of scientific and technical activities are shown by the selected examples that follow:

Program	1993 Actual	1994 Estimated	1995 Estimated
ADC methods development:			
Registration/Reregistration:			
Number of data submissions.....	45	51	50
Number of quarterly, annual, and consortia progress reports.....	40	32	34
Number of registration applications.....	25	25	27
Number of investigational new animal drug application - (requires FDA approval).....	-	1	-
Number of data "call-in" - (data collected on pesticides (chemical-repellents) for EPA reregistration).....	5	4	11
Research:			
Studies initiated.....	72	60	60
Studies completed.....	30	40	42
Studies in progress.....	95	90	92
Publications.....	60	74	59
Biotechnology/Environmental Protection:			
Number of release permit applications received:			
Release.....	89*	90	100
Importation.....	57	60	75
Movement.....	177	75	125
Number of release permits issued:			
Release.....	89	85	95
Importation.....	53	60	75
Movement.....	172	75	125
Number of days to process:			
Release.....	45	75	90
Importation.....	33	45	45
Movement.....	33	45	45
Number of notifications received (since inception of process, 5/1/93) for corn, cotton, potato, soybean, tobacco, tomato:			
Release.....	213**	700	1,200
Importation.....	23	10	12
Movement.....	147	400	600
Number acknowledged:			
Release.....	189	665	1,140
Importation.....	17	10	12
Movement.....	133	350	575
Number of days to acknowledge:			
Release.....	27	25	25
Importation.....	11	10	10
Movement.....	9	8	8
Technical and Scientific Services (NMRAL):			
Number of program samples analyzed.....	3,993	4,500	4,500
Number of contract samples analyzed.....	5,811	7,000	7,000
* Includes release renewal permits. Maximum 120-day review period.			
** Includes 63 permits "rolled over" into notification when the latter option became available. Thirty day period required between receipt and initiation of release. Acknowledgement may occur prior to the 30-day maximum period.			

Plant methods development:			
Aerial pesticide application technology tests.....	1	5	4
Asian gypsy moth:			
Formal presentations.....	5	6	6
Manuscripts.....	1	3	10
Research experiments.....	17	20	20
Consultations.....	100	100	50
Gypsy moth:			
Formal presentations.....	12	12	12
Manuscripts.....	3	4	4
Pheromone trials.....	5	10	5
Aerial pesticide technology development tests.....	8	10	10
Insecticide formulation tests in the laboratory.....	28	30	30
Consultations.....	102	102	102
Biological control:			
Formal presentations.....	9	12	12
Impact evaluation.....	5	8	8
Research experiments.....	7	11	11
Cooperative studies.....	3	8	8
Consultations.....	10	17	17
Exotic pest survey:			
Formal presentations.....	3	4	4
Pheromone trials.....	2	4	5
Consultations.....	64	64	64
Production of survey dispensers.....	45,000	50,000	50,000
Consultations on exotic pest survey methods.....	83	103	103
Grasshopper:			
Formal presentations.....	2	2	2
Bio-insecticide formulations tested in the field.....	1	1	15
Bio-insecticide laboratory tests.....	10	10	10
Insecticide formulations tested in the field.....	3	—	3
Insecticide formulations tested in the laboratory.....	1	3	3
Field evaluations of IPM treatments.....	7	7	7
Individual training for grasshopper identification.....	3	3	3
IPM technology transfer team activities/sessions.....	5	6	6
Manuscripts.....	2	1	1
Identification techniques:			
Formal presentations.....	2	4	4
Research experiments.....	23	25	25
Cooperative studies.....	7	10	10
Insect identifications.....	7,250	5,000	5,000
Consultations.....	60	70	70
Imported fire ant:			
Formal presentations.....	21	20	20
Manuscripts.....	8	5	5
Experiments.....	45	50	50
Insecticidal treatments evaluated.....	21	25	25
Consultations.....	200	200	200
Mediterranean fruit fly:			
Traps and Lure Tests.....	14	18	18
Mass rearing and SIT.....	15	22	24
Competitiveness Tests.....	9	12	10
Consultations.....	30	45	45
Mexican fruit fly:			
Field trials conducted of new traps and lures.....	7	9	9
Aerial pesticide and technology tests.....	—	3	2
Mass-rearing and sterile release technology.....	6	7	9
Noxious weeds:			
Formal presentations.....	25	28	31
Manuscripts.....	14	16	16
Research experiments.....	55	65	65
Species projects.....	50	60	65
Consultations.....	223	275	300
Pine shoot beetle:			
Formal presentations.....	4	6	6
Manuscripts.....	1	1	3
Research experiments.....	10	10	15
Consultations.....	25	50	50
Regulatory treatments investigated.....	15	15	5
Pink bollworm:			
Formal presentations.....	3	3	3
Shipments of test insects.....	125	150	150
Pheromone system field trials.....	3	2	4
Mass-rearing assistance to major field trials.....	30	30	30

Whitefly:			
Formal presentations	3	3	3
Manuscripts and reports	3	4	4
Evaluation of area-wide management projects	2	2	4
Predator colonies remained	1	2	1
Predator field tests	5	5	5
Parasite release and evaluation	2	4	4
Witchweed:			
Formal presentations	25	15	15
Manuscripts	14	13	13
Research experiments	45	26	16
Herbicidal treatments investigated	55	40	20
Consultations	170	185	210
Technical support	28	30	30
Veterinary biologics:			
Number of serials processed for release	22,741	17,000*	12,500
Number of serials submitted for pre-release check testing	10,506*	11,500	12,500
Percent of serials tested for:			
Potency	8.9	8.0	8.0
Purity	4.2	4.0	4.0
Sterility	4.2	4.0	4.0
Safety	0.03	0.03	0.03
Chemistry	0.3	0.3	0.3
Number of inspections:			
In-depth	68	55	70
Follow-up	12	10	10
Special	36	35	35
Percent of inspections that find unsafe practices	57	55	60
* Reduction in total numbers due to removal of release and check-testing requirements for first-serial autogenous biologics.			
Veterinary diagnostics:			
Number of import-export health requirement tests conducted at National Veterinary Service Laboratories (NVSL)	70,000	70,000	70,000
Number of import-export health requirement tests conducted at Foreign Animal Diseases Diagnostic Laboratories (FADDL)	21,000	22,000	22,000
Number of fraudulent blood screening tests conducted	70,000	70,000	70,000
Number of diagnostic tests conducted at NVSL	485,000	500,000	500,000
Volume of reagents shipped (milliliters):			
By NVSL	3,200,000	3,300,000	3,300,000
By FADDL	200,000	200,000	200,000
Number of training days provided:			
International students	425	450	450
Domestic students	280	300	300

GAO AUDITS

<u>Report No.</u>	<u>Title</u>	<u>Date Issued</u>
RECD-93-22	Food Safety: "Building A Scientific Risk Based Meat & Poultry Inspection System"	3/1/93

OIG AUDITS

<u>Report No.</u>	<u>Title</u>	<u>Date Issued</u>
50600--AT	Federal Employees Compensation Act Program	3/2/93
50566-0017-CH	Single Audit of the State of Minnesota	9/30/93

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50568-263-KC	Audit of the State of Montana, Helena, Montana, for 2-year period ended June 30, 1991	7/13/93
50566-25-SF	A-128, State of Idaho	2/5/93
50566-28-AT	A-128, State of Alabama	3/2/93
33097-7-KC	Animal Damage Control, Cooperative Agreements	5/7/93

JUSTIFICATION OF INCREASES AND DECREASES

- (1) A net increase of \$10,416,000 for pest and disease exclusion activities, consisting of:

- (a) An increase of \$1,163,000 for the Fiscal Year (FY) 1995 pay costs of 1.6 percent.
- (b) An increase of \$1,806,000 for the increase in non-salary costs of 2.6 percent.
- (c) A decrease of \$873,000 for the reduction in Federal employment costs.

Need for Change. The Secretary has developed a plan to streamline the department in support of the President's Executive Order mandating a reduction of Federal employees.

Nature of Change. To achieve the reduction target, APHIS will eliminate 17 staff years (4.9%), excluding AQI staff years, by the end of FY 1995. In addition, APHIS will be working with the other Marketing and Inspection Agencies to evaluate whether additional offices could be closed, consolidated or collocated.

- (d) A decrease of \$1,806,000 for administrative efficiency.

Need for Change. The Secretary's plan to streamline the administrative functions in Marketing and Inspection Service agencies includes consolidating these functions into four centers of excellence beginning in 1994.

Nature of Change. In order to achieve these administrative savings, APHIS will be responsible for increasing the efficiency of providing the administrative functions. AMS will be responsible for increasing the efficiency of providing the information resources and financial management functions. And, FSIS will be responsible for increasing the efficiency of providing the personnel functions. These efficiencies will reduce the cost of recruitment, travel, supplies, printing and reproduction, utilities, automation, program cost accounting, training, rent, and cooperative agreements.

- (e) An increase of \$643,000 for the agricultural quarantine inspection (AQI) appropriated program (\$24,246,000 available in FY 1994).

Need for Change. The AQI appropriated program protects American agriculture from exotic pests and diseases by supporting Mexican border activities, inspecting private and military aircraft and small tonnage vessels, and miscellaneous activities not funded by user fees. The program is designed to enhance exclusion of fruit flies, khapra beetle, and other exotic plant and animal pests and diseases. APHIS inspects passengers departing Puerto Rico and Hawaii for the U.S. mainland, as well as pedestrians and passenger motor vehicle traffic from Mexico.

Each person, bag, or cargo item entering this country could carry an exotic pest capable of causing a major outbreak. APHIS experienced almost 2 million passenger increase in predeparture inspections over the past 5 years in Hawaii and Puerto Rico, with minimal staffing.

Nature of Change. The increased funding will allow APHIS to better protect the mainland by providing additional staffing and equipment to high volume ports of entry and to those susceptible to tropical fruit fly infestations, such as those in Hawaii and Puerto Rico.

- (f) An increase of \$9,657,000 for the AQI user fees program (\$91,460,000 available in FY 1994).

Need for Change. The principal objective of the AQI user fee program is to prevent pests and diseases of foreign origin from entering the United States and spreading within the country. APHIS experienced an increase in passenger inspections from 41 million in FY 1991 to 47 million in FY 1993. During this same time period, carrier inspections increased by over 24,000. Staffing increases in existing ports have expedited passenger inspections while improving APHIS' ability to detect pests. In addition, in FY 1995 new terminals are scheduled to open in Atlanta, Georgia, and Denver, Colorado.

Nature of Change. This increase would allow improvements in several key areas including permanent staffing, equipment, and automation. The AQI cargo inspection program will run more efficiently with the help of a nationwide automated tracking system, and the airport inspection program could provide improved coverage and more thorough inspections nationally and internationally.

- (g) A decrease of \$227,000 for import/export activities (\$6,800,000 available in FY 1994).

Need for Change. The program goals are to protect U.S. animal and poultry populations against the introduction of exotic animal diseases and their vectors; facilitate and ensure exportation of animals, poultry, and related products that are free of communicable diseases; and protect U.S. markets abroad.

By mid-FY 1994, additional user fees will be implemented, resulting in additional revenue to support import/export activities. These fees will enable the program to recover costs associated with providing inspection services at ports of entry for all animals presented for importation into the United States. In addition, the fees would cover costs for animal product importations, including the cost of issuing product permits and inspections at product establishments.

Nature of Change. APHIS will continue with planning activities related to the implementation of international regionalization agreements, but at a reduced level. This will enable the USDA to demonstrate its commitment to risk assessment. Staffing increases would not be provided for the National Center for Import-Export. APHIS will reduce the number of staff working on regionalization and risk assessment.

- (h) An increase of \$338,000 for international program activities (\$5,826,000 available in FY 1994).

Need for Change. The goal of international programs is to provide leadership, management, and coordination of international activities pertaining to phytosanitary and zoosanitary measures and facilitate international trade. As international trade opportunities expand and

more countries participate in that trade, it is essential that APHIS work closely with emerging and developing countries.

Each year APHIS is required to reimburse the State Department for Foreign Affairs Administrative Support (FAAS) services. The FAAS system is a method of determining administrative support costs and distributing these costs among participating foreign affairs agencies overseas. FAAS services include but are not limited to medical services, regional security, imprest fund, housing, general support services, foreign service nationals, personnel services, motor pool, messenger services, and mail services. Funding for increased FAAS costs is necessary to avoid erosion of base funding for program activities.

Nature of Change. APHIS would increase technical information exchange with emerging and developing countries, which will benefit worldwide phytosanitary and zoosanitary conditions. In addition, APHIS will continue implementation of planned cross-training of international APHIS personnel on both plant and animal health issues. The request will also fund an estimated \$103,000 in increased costs of services provided to APHIS under FAAS.

- (i) A decrease of \$97,000 for the Mexican fruit fly program, (\$2,272,000 available in FY 1994).

Need for Change. Successful cooperative efforts under the Mexican national fruit fly plan and eradication program have caused the number of Mexican fruit fly (MFF) detections in the Baja California Sur area to fall significantly during FY 1993. Because of this progress, APHIS is able to scale back program activities in this region.

Nature of Change. APHIS would eliminate one or two field personnel positions, and would reduce support for sterile MFF production and releases by 10 percent in the Baja, California area. Trapping and supervision of Mexican trapping activities would be reduced. Cooperators will be asked to increase their contribution to help maintain program progress. Additionally, international and domestic activities are currently being coordinated and re-evaluated to minimize program impact resulting from reduced funding.

- (j) A decrease of \$188,000 for the screwworm program, (\$34,645,000 available in FY 1994).

Need for Change. The screwworm program is a cooperative eradication effort established to prevent screwworms from entering the United States, by eradicating screwworms in Central America and establishing a permanent sustainable barrier at the Darien Gap in Panama. This will prevent northward movement of the pests from South America. Program objectives are accomplished through sterile fly dispersal, surveillance, quarantine, and livestock wound treatment. APHIS has identified the establishment of a barrier in Panama as the most cost effective strategy to protect the livestock industry from screwworms. While this is an imperative Agency goal, some flexibility in the program time-line permits activities to be scaled back to help sustain other APHIS activities which have less flexibility.

Nature of Change. APHIS would slightly decrease sterile fly production for the screwworm program. The program schedule to release flies in Costa Rica by mid FY 1995 would be extended by one quarter, and therefore would begin in the third quarter of FY 1995. The goal of establishing a barrier in Panama would be extended by one quarter, to the fourth quarter of FY 1996.

(2) A net increase of \$199,000 for plant and animal health monitoring activities, consisting of:

- (a) An increase of \$383,000 for the FY 1995 pay costs of 1.6 percent.
- (b) An increase of \$715,000 for the increase in non-salary costs of 2.6 percent.
- (c) A decrease of \$1,031,000 for the reduction in Federal employment costs.

Need for Change. The Secretary has developed a plan to streamline the department in support of the President's Executive Order mandating a reduction of Federal employees.

Nature of Change. To achieve the reduction target, APHIS will eliminate 21 staff years (2.4%) by the end of FY 1995. In addition, APHIS will be working with the other Marketing and Inspection Service Agencies to evaluate whether additional offices could be closed, consolidated or collocated.

- (d) A decrease of \$715,000 for administrative efficiency.

Need for Change. The Secretary's plan to streamline the administrative functions in Marketing and Inspection Service agencies includes consolidating these functions into four centers of excellence beginning in 1994.

Nature of Change. In order to achieve these administrative savings, APHIS will be responsible for increasing the efficiency of providing the administrative functions. AMS will be responsible for increasing the efficiency of providing the information resources and financial management functions. And, FSIS will be responsible for increasing the efficiency of providing the personnel functions. These efficiencies will reduce the cost of recruitment, travel, supplies, printing and reproduction, utilities, automation, program cost accounting, training, rent, and cooperative agreements.

- (e) An increase of \$47,000 for the Animal and Plant Health Regulatory Enforcement program (\$5,849,000 available in FY 1994).

Need for Change. APHIS' Regulatory Enforcement program maintains a network of trained field investigators who conduct investigations of reported violations of APHIS regulations. The volume of cases associated with APHIS regulated programs such as animal welfare, agricultural quarantine inspection, plant protection and quarantine, and veterinary services continues to grow along with the complexity of investigations involving fraudulent blood, smuggling of prohibited plant or animal products, stolen dogs, and institutional animal care and use committee violations.

Nature of Change. The new aquaculture and pre-harvest pathogen reduction line-items also increase the volume and complexity of Regulatory Enforcement's case load. This line item will coordinate APHIS' contribution of \$0.2 million for the regulatory science Center of Excellence at Pine Bluff, Arkansas.

- (f) An increase of \$800,000 for the pest detection program (\$3,444,000 available in FY 1994).

Need for Change. The Pest Detection program provides improved information on plant pests and diseases, to support the competitive position of U.S. agricultural products in global markets. The

competitive position of agricultural products is enhanced in three ways: 1) Effective surveys provide early detection of exotic pests soon after their introduction to a new geographic range. This allows eradication programs to prevent the permanent establishment of pests or diseases in cropping systems. 2) When our phytosanitary officials possess accurate information on the presence or absence of species which are regulated in international trade, they can negotiate the most favorable positions in our trade agreements. 3) Production and protection costs of agricultural products include significant sums for pest management. Accurate and timely biological information supports decisionmaking which maximizes the efficiency of pest management expenditures. Computerized databases, communications networks, and advanced technologies such as global positioning systems and geographic information systems provide ways to increase the efficiency of pest surveys and management of the resulting data.

Additionally, the General Agreement on Tariffs and Trade negotiations and the North American Free Trade Agreement may lead to reductions in tariff or other traditional economic barriers and subsequently raise the importance of phytosanitary considerations in international trade agreements. There is also a need for pest surveillance in Mexico and the Caribbean to protect U.S. Agriculture and to support the risk assessments that allow agricultural trade.

Nature of Change. Increased funding will strengthen the network of Cooperative Agricultural Pest Survey (CAPS) by providing States and protectorates additional resources for survey and data management activities. Activities will be directed toward crops and forests which are at risk of infestation by exotic pest species and emphasize crops which lack export competitiveness because of insufficient data on the geographic range of their domestic pests. The increased funding will enable APHIS to conduct cooperative detection surveys for up to five exotic pest species in up to 15 States, with moderate probability of detecting an infestation within 8 years of introduction. CAPS cooperators will conduct surveys, aggregate data, utilize spatial data support systems, and provide improved information to phytosanitary officials thereby enhancing the export competitiveness of agricultural products.

Funds will also be used to support fruit fly surveys on one Caribbean Island that has not prepared baseline detection work, through transfer of technology and technical assistance. APHIS will review and support existing detection programs in countries where initial surveys were conducted, such as the Dominican Republic, Trinidad, and Grenada. APHIS will also participate in another critical survey in the western hemisphere, such as for brown citrus aphid, citrus tristeza virus, chrysanthemum white rust, khapra beetle, or exotic fruit fly.

- (3) A net decrease of \$12,984,000 for pest and disease management activities, consisting of:
- (a) An increase of \$660,000 for the FY 1995 pay costs of 1.6 percent.
 - (b) An increase of \$1,127,000 for the increase in non-salary costs of 2.6 percent.
 - (c) A decrease of \$1,296,000 for the reduction in Federal employment costs.

Need for Change. The Secretary has developed a plan to streamline the department in support of the President's Executive Order mandating a reduction of Federal employees.

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Nature of Change. To achieve the reduction target, APHIS will eliminate 26 staff years (1.6%) by the end of FY 1995. In addition, APHIS will be working with the other Marketing and Inspection Service Agencies to evaluate whether additional offices could be closed, consolidated or collocated.

- (d) A decrease of \$1,127,000 for administrative efficiency.

Need for Change. The Secretary's plan to streamline the administrative functions in Marketing and Inspection Service agencies includes consolidating these functions into four centers of excellence beginning in 1994.

Nature of Change. In order to achieve these administrative savings, APHIS will be responsible for increasing the efficiency of providing the administrative functions. AMS will be responsible for increasing the efficiency of providing the information resources and financial management functions. And, FSIS will be responsible for increasing the efficiency of providing the personnel functions. These efficiencies will reduce the cost of recruitment, travel, supplies, printing and reproduction, utilities, automation, program cost accounting, training, rent, and cooperative agreements.

- (e) A decrease of \$2,558,000 for animal damage control operations activities (\$26,092,000 available in FY 1994).

Need for Change. This program uses a combination of Federal and matching money from States, counties, and others to prevent and reduce damage caused by wildlife primarily to agricultural and natural resources as well as to human health and safety. Wildlife damage control programs are managed by APHIS' professional wildlife biologists.

A significant part of APHIS' mission is to protect American agriculture and other resources through identification, demonstration, and application of effective methods that control wildlife and other free-ranging animals, thereby minimizing their adverse impact on agricultural production, wildlife preservation, and public safety. However, persistent Federal deficits dictate that some APHIS programs must be reduced in order to achieve deficit reduction goals.

Nature of Change. APHIS would reduce current programs involving direct control and will not pursue new cost sharing initiatives. The Agency would rely on States and private entities to assume greater responsibility for activities involving direct control of damage by predators such as coyotes, beavers, blackbirds, and other species which damage the agricultural community. APHIS will implement new and more socially acceptable control methods to reduce wildlife damage and work to achieve compliance with NEPA requirements.

- (f) An increase of \$493,000 to establish an aquaculture program (no program in FY 1994).

Need for Change. Commercial aquaculture is the most rapidly growing segment of U.S. agriculture. Coinciding with this growth has been the proliferation of fish-eating birds which has increased the level of conflict between the bird populations and this industry. States are now recognizing aquaculture as a segment of agriculture, and many are assigning regulatory and developmental assistance responsibilities to their departments of agriculture.

Nature of Change. APHIS would establish a program to reduce bird damage to aquaculture while ensuring the continued viability of migratory birds in the United States. The Agency would increase its efforts to implement control methods to reduce bird and aquaculture conflicts, coordinate biological survey data, develop bird damage management plans, provide technical assistance to producers, develop a cooperatively funded control program, coordinate depredation permits with the Fish and Wildlife Service and the State wildlife agencies, establish liaison with wild fishery interests, and evaluate current control methods and develop new ones as necessary.

- (g) An increase of \$2,000,000 for the biological control (biocontrol) program (\$5,702,000 available in FY 1994).

Need for Change. The APHIS biocontrol program is an important part of the Federal and State cooperative effort to acquire, produce, and distribute biological agents for Russian wheat aphid (RWA), leafy spurge, diffuse and spotted knapweed, Colorado potato beetle, cereal leaf beetle, and euonymus scale. Biological control constitutes an ecologically based, efficient pest management tactic that is fully compatible with other components of modern integrated pest management. Also, it is an environmentally sound approach to existing and future pest control strategies. In FY 1991 the RWA was first funded as a separate line item. The removal of the RWA project from the biological control line item has caused funding for the aphid biological control project to become fragmented. The remaining aphid project activities have been funded through the biological control line item. Since both projects use the same facilities and most of the same scientific staff, APHIS would prefer to fund both programs from a single source. In addition, APHIS is proposing to phase down and eliminate separate funding for the sweet potato whitefly (SPW) project.

Nature of Change. APHIS would consolidate funding for the RWA program under the biological control line item. Remaining activities in support of sweet potato whitefly eradication will also be funded through this line item. A total of \$44,000 of the increase and \$206,000 of existing funding will support SPW activities, for a total of \$250,000. Maintenance of some exotic natural enemy cultures, recently imported at the National Biological Control Laboratory in Mission, Texas, will be available to the research community and State cooperators.

- (h) A decrease of \$5,018,000 for the brucellosis program (\$31,004,000 available in FY 1994).

Need for Change. The brucellosis eradication program is a cooperative venture in which the Federal government may provide up to 60 percent of the funding and States must provide at least 40 percent. The brucellosis eradication program is operating under the industry supported Rapid Completion Plan (RCP). The success of the eradication program is significant. Nationwide there are 32 States, plus the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, in Class "Free" status; 17 States in Class "A" status; and only one State in Class "B." The number of herds under quarantine continues to decrease. As of September 30, 1993, there were 283 herds under quarantine for brucellosis compared to 487 herds at the end of September 1992.

Nature of Change. APHIS will continue to pursue the goal of brucellosis eradication at a reduced level, including a reduction of approximately 29 staff years. Depopulation funds will be available to eliminate brucellosis from a limited number of herds having unusually

high or persistent levels of infection. APHIS would conduct first point of concentration testing in two high incidence States. The goal for eradicating brucellosis would be extended beyond FY 1998.

- (i) An decrease of \$40,000 for the golden nematode program (\$658,000 available in FY 1994).

Need for Change. The goal of the program is to prevent the spread of the golden nematode to new locations outside the infested areas in New York State, and to reduce the level and number of infestations within the regulated areas. APHIS is accomplishing this goal by developing a biologically based management program that will allow growers to reduce golden nematode levels in currently infested areas.

Many residential and commercially developed properties within the regulated areas have not been removed from the list of infested property. APHIS, in conjunction with State regulatory officials, is reviewing the list of infested properties to remove those properties where potatoes will no longer be grown. In addition, APHIS continues to encourage New York State officials to require growers with exposed properties to adopt the management program. The management program includes crop rotation, cultural practices, and the use of golden nematode resistant potato varieties. This should result in a significantly reduced number of new infestations. As growers succeed in eliminating infestations, the need for surveys in New York State will diminish.

Nature of Change. Properties that no longer present risk will be removed from the list of infested property. In addition, APHIS will turn a portion of the golden nematode survey program over to the State.

- (j) A decrease of \$380,000 to eliminate the honey bee pests program (\$380,000 available in FY 1994).

Need for Change. In FY 1991, APHIS shifted the focus of the Africanized honey bee (AHB) program to providing public information, identification and monitoring support, and technology transfer. In FY 1993, APHIS completed its three-phase monitoring plan for tracking the movement of AHB. Through the cooperative National Honey Bee Certification Program, the responsibility of AHB monitoring has been transferred to States and local agencies.

Nature of Change. The USDA, Extension Service, will continue to have the lead role in disseminating information on new or improved agricultural practices and technologies in managing honey bees in an AHB environment. APHIS will coordinate the monitoring of AHB and provide expertise to the States when requested. These activities will be funded by the miscellaneous plant pests program.

- (k) A decrease of \$2,700,000 to eliminate the imported fire ant program (\$2,700,000 available in FY 1994).

Need for Change. Since 1977, no control substance that is registered for use on most agricultural lands has proven effective against the IFA. Since 1985, the Agency has not received any requests from States for cooperative treatment programs, and many States have proven themselves able to successfully eradicate small isolated infestations outside the regulated area. Areas currently regulated include: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, and Texas.

Nature of Change. APHIS would eliminate this line item since no effective, efficient, and environmentally acceptable control agents are available. All regulatory and survey activities would be conducted by the States. APHIS will continue to evaluate the efficacy of regulatory treatments for preventing further artificial spread of the IFA under the plant methods development line item.

- (l) A decrease of \$67,000 for the noxious weeds program (\$475,000 available in FY 1994).

Need for Change. APHIS works with State and local agencies to detect noxious weeds and prevent them from damaging U.S. agriculture. The program began in 1979 with surveys in 25 States and Puerto Rico, port-of-entry inspections, hydrilla control in Florida, and the formation of a technical committee to evaluate noxious weeds. In recent years, funding was provided for control and eradication efforts directed at common crupina, goatsrue, hydrilla, and weed identification, but not for comprehensive surveys. However, the States' cooperation in the control and eradication of noxious weeds and the program successes in the goatsrue and hydrilla programs allowed a decrease in funding for the noxious weed program in FY 1993. In FY 1994, the focus of the goatsrue program will be redirected from eradication to control.

Nature of Change. Program goals for eradication programs, such as the goatsrue program in Utah and the common crupina programs in Washington and Oregon, will be redirected from eradication to control. This will reduce field activity resulting in the need for less supplies, equipment, and personnel.

- (m) A decrease of \$1,217,000 for the pink bollworm program (\$2,292,000 available in FY 1994).

Need for Change. APHIS, California, and cotton producers operate a sterile moth rearing facility in Phoenix, Arizona. In FY 1990, the cotton producers purchased a replacement facility for the sterile moth rearing operation. Funds were appropriated in FY 1991, 1992, and 1993 to purchase equipment for the replacement facility, and to prepare the building for installation of the equipment. By the end of FY 1993, APHIS purchased the equipment needed to match the production capacity of the old rearing facility.

Nature of Change. Expanded production capacity would be necessary if APHIS conducted a 3 year Integrated Pest Management demonstration project using pheromone systems, sterile moth release, and short-season cultural practices; however, due to budget constraints the demonstration project has been postponed. APHIS will not purchase equipment needed to expand the production capacity of the sterile moth rearing facility in FY 1995.

- (n) An increase of \$5,702,000 to establish the preharvest pathogen reduction program (no program in FY 1994).

Need for Change. The goal of the program is to enhance the safety and wholesomeness of animal food products. Preharvest food safety programs are needed to prevent human foodborne illnesses by reducing biological and chemical pathogens at the farm level. The program goal will initially focus on risk assessment techniques, Hazard Analysis and Critical Control Point (HACCP) systems (a method of focusing on areas where changes will have a positive effect), data collection and analysis, identification and traceback, and monitoring and surveillance. APHIS, with its network of epidemiologists, experience in working with producers at the farm level, and a field and laboratory

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network of veterinarians, scientists, and animal health technicians, is ideally positioned to carry out these activities. This proactive approach to increase the overall awareness of food safety factors on the farm-to-table continuum will lead to increased consumer confidence in the safety of the food supply and strengthen USDA's ability to oversee the food production process. Also, by achieving higher food safety standards than our trading competitors, U.S. producers will have a decided advantage in securing competitive international markets.

Nature of Change. Funding would support implementation of a preharvest pathogen reduction program, allowing APHIS to become an active partner with the Food Safety and Inspection Service (FSIS) and other agencies with food safety responsibilities. There will be active collaboration with FSIS and public health officials to trace back and investigate foodborne disease outbreaks such as E. Coli O157:H7, Listeria monocytogens, and campylobacter. APHIS would expand diagnostic testing for potential foodborne pathogens using samples generated by existing monitoring and surveillance activities. APHIS would conduct tracebacks and investigations on some foodborne disease outbreaks. Also, funding would allow for the redesign of an identification and recordkeeping system that would enhance premises of origin and individual animal identification. In addition, funding provides for a Center of Excellence at the University of Maryland - Eastern Shore. The Center will focus on reducing risks of microbiological contamination in poultry and poultry products at all stages of the farm-to-table food safety continuum, with particular emphasis on the preharvest level.

- (o) A decrease of \$1,098,000 for the pseudorabies eradication program (\$4,543,000 available in FY 1994).

Need for Change. APHIS fully supports this cooperative State-Federal-industry program to eradicate pseudorabies. However, the Agency believes that the program expertise maintained by the States and industry, the increased role in the program that certain States have adopted, and recent program successes will enable the Agency to make great strides toward accomplishing the goals of the industry-developed eradication plan. Among recent program successes in FY 1993, 21 States in addition to Puerto Rico and the U.S. Virgin Islands progressed to the next stage in the pseudorabies program and seven States (Alaska, Connecticut, Maine, Mississippi, New Mexico, Utah, and Wyoming) advanced to Stage V (Free) status. All States except for Iowa have progressed in their eradication programs and the number of infected hogs in these States has been decreasing since June 1990. The United States now has its lowest level of infected herds since the pseudorabies program began in 1988.

In FY 1994, the monitoring and surveillance activities associated with the pseudorabies program were transferred to the new animal health monitoring and surveillance line item and the pseudorabies line item continued to fund eradication activities.

Nature of Change. APHIS will continue to provide direct support for local programs to eradicate pseudorabies, but at a reduced level. The Agency will continue to provide national program coordination, technical advice, regulatory assistance, public information, and recordkeeping. The eradication goal would likely be extended beyond 2000.

- (p) A decrease of \$2,400,000 for the Russian wheat aphid (RWA) line item (\$2,400,000 available in FY 1994).

Need for Change. Since the RWA program is dedicated to biological control technologies in APHIS, and utilizes the same staff and facilities involved in biological control programs, the Agency believes that the RWA program should be merged into the biological control line item.

Nature of Change. APHIS will no longer fund the RWA program as an individual line item. In FY 1995, program activities will be supported under the biocontrol program. The biocontrol line item includes \$2.0 million to continue the RWA program.

- (q) A decrease of \$3,514,000 to eliminate the sweet potato whitefly (SPW) program (\$3,514,000 available in FY 1994).

Need for Change. A SPW outbreak occurred in California in November 1991 and prompted an emergency declaration to combat the pest. APHIS requested and Congress provided a SPW line item in FY 1993 to facilitate the introduction of exotic natural enemies of the pest into the United States to significantly reduce SPW populations and insecticide use. Due to expedited and intensified program efforts in collaboration with ARS and State cooperators in FY 1993 and FY 1994, APHIS expects to provide exotic natural enemies of SPW to Federal and State cooperators and the private sector by FY 1995. This will allow the cooperators to mass produce and distribute all exotic natural enemies at the local level and evaluate the impact, thereby allowing for a reduction in funds for SPW in FY 1995.

Nature of Change. The decrease in funds will significantly reduce the Federal role in the SPW program. Some exotic natural enemy cultures recently imported at the National Biological Control Laboratory in Mission, Texas, will be maintained and made available to the research community and State cooperators. Foreign exploration for exotic natural enemies of SPW will not occur. Phasing down of the program will include minimal production, release, and field evaluation of the release and efficacy of imported natural enemies and their integration into alternative pest management strategies and laboratory cultures. SPW efforts will be supported with a total of \$500,000 contributed equally from both the plant methods development and the biocontrol line items.

- (r) An increase of \$537,000 to establish a Tropical Bont Tick program (no program in FY 1994).

Need for Change. The program goal is to protect the United States from the introduction of heartwater, a disease vectored by the tropical bont tick (TBT). This would be carried out through participation in an international effort to eradicate the TBT from the Caribbean Islands. The TBT threat is similar to that posed by cattle fever ticks. Losses in the early 1900's due to ticks totaled \$40-\$60 million annually and losses today could reach \$500 million annually. Despite extensive local control programs, the TBT continues to spread in the Caribbean, now infesting 19 islands. As TBT spreads in the Caribbean, the threat of introduction into the United States increases. Because TBT is an important vector for heartwater disease, the problem is magnified. Heartwater is already well established in three Caribbean islands, with serological evidence that it is present on nine others. Heartwater disease, and its vector the tropical bont tick, pose a threat not only to Caribbean livestock industries but also to much of the Western Hemisphere.

In FY 1991, the National Cattlemen's Association, fearing the spread of TBT and heartwater to the United States, passed a resolution supporting

APHIS' direct involvement in TBT eradication from the Caribbean. By strengthening animal health within the hemisphere and the agricultural infrastructures of the Caribbean countries, APHIS would be actively facilitating trade movement and would greatly enhance the exclusion and surveillance programs of the hemisphere as a whole. Conversely, if the TBT and its associated diseases go unchecked in the Caribbean, they could establish themselves throughout the region and eventually spread to the mainland of North, Central, and South America, causing a negative economic impact on a much larger scale.

Nature of Change. APHIS would initiate a pilot program for control of heartwater disease in the Caribbean through selective eradication of the TBT. APHIS would begin to work with the Food and Agriculture Organization of the United Nations, the Inter-American Institute for Cooperation on Agriculture, and the Economic Community of Caribbean Countries, as part of regional efforts aimed at controlling the spread of the tick and eradicating it from infested islands. APHIS will focus its efforts on the northern Caribbean islands. The Agency will place a full-time director of operations and a part-time information specialist.

- (s) A decrease of \$2,088,000 for the witchweed program (\$4,081,000 available in FY 1994).

Need for Change. The program's goal is to prevent the spread of witchweed to host crop producing areas in the United States and move toward eventual eradication of the pest. Witchweed is a parasitic plant that attacks corn, sorghum, sugarcane, rice, and more than 60 species of the grass family. Witchweed can significantly reduce crop yields by robbing its host of nutrients and water. APHIS plans a phase down of the witchweed eradication program. From 1991 to 1993, the program reduced by 67 percent witchweed infested acreage, leaving about 40,000 infested acres. In FY 1994, APHIS plans to eradicate witchweed from 10,000 of the remaining infested acres.

Nature of Change. The decrease is consistent with the planned phase down of the program. As less acres remain to be eradicated, fewer personnel will be needed to operate the program. APHIS will continue to conduct survey, regulatory, and control activities to reduce witchweed infested acreage. Approximately 6,000 of the remaining 30,000 acres will be treated using control measures, such as specific herbicides, soil fumigants, and a seed stimulant. This will leave approximately 24,000 acres to be eradicated in FY 1996.

- (4) A net decrease of \$178,000 for animal care activities, consisting of:
- (a) An increase of \$76,000 for the FY 1995 pay costs of 1.6 percent.
 - (b) An increase of \$101,000 for the increase in non-salary costs of 2.6 percent.
 - (c) A decrease of \$137,000 for the reduction in Federal employment costs.

Need for Change. The Secretary has developed a plan to streamline the department in support of the President's Executive Order mandating a reduction of Federal employees.

Nature of Change. To achieve the reduction target, APHIS will eliminate 3 staff years (1.6%) by the end of FY 1995. In addition, APHIS will be working with the other Marketing and Inspection Service Agencies to evaluate whether additional offices could be closed, consolidated or collocated.

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(d) A decrease of \$101,000 for administrative efficiency.

Need for Change. The Secretary's plan to streamline the administrative functions in Marketing and Inspection Service agencies includes consolidating these functions into four centers of excellence beginning in 1994.

Nature of Change. In order to achieve these administrative savings, APHIS will be responsible for increasing the efficiency of providing the administrative functions. AMS will be responsible for increasing the efficiency of providing the information resources and financial management functions. And, FSIS will be responsible for increasing the efficiency of providing the personnel functions. These efficiencies will reduce the cost of recruitment, travel, supplies, printing and reproduction, utilities, automation, program cost accounting, training, rent, and cooperative agreements.

(e) A decrease of \$117,000 for the horse protection program (\$481,000 available for FY 1994).

Need for Change. Congress increased the horse protection appropriation by \$120,000 in FY 1994 to procure thermograph machines for the purpose of evaluating their effectiveness as an additional diagnostic tool to detect sores. The thermograph machine visually records and analyzes thermal heat energy naturally radiating from the lower leg of a horse. After the machines are acquired and employed in FY 1994, APHIS must then analyze their effectiveness as a program tool before making a decision to request funds for purchase of additional machines.

Nature of Change. This change would allow APHIS to continue ongoing field operations of the horse protection program at the existing level. Funds are not requested for acquisition of additional thermograph machines or related training in FY 1995.

(5) A net decrease of \$618,000 for scientific and technical service activities, consisting of:(a) An increase of \$311,000 for FY 1995 pay costs of 1.6 percent.(b) An increase of \$526,000 for the increase in non-salary costs of 2.6 percent.(c) A decrease of \$669,000 for the reduction in Federal employment costs.

Need for Change. The Secretary has developed a plan to streamline the department in support of the President's Executive Order mandating a reduction of Federal employees.

Nature of Change. To achieve the reduction target, APHIS will eliminate 13 staff years (1.8%) by the end of FY 1995. In addition, APHIS will be working with the other Marketing and Inspection Service Agencies to evaluate whether additional offices could be closed, consolidated or collocated.

(d) A decrease of \$526,000 for administrative efficiency.

Need for Change. The Secretary's plan to streamline the administrative functions in Marketing and Inspection Service agencies includes consolidating these functions into four centers of excellence beginning in 1994.

Nature of Change. In order to achieve these administrative savings, APHIS will be responsible for increasing the efficiency of providing the administrative functions. AMS will be responsible for increasing the efficiency of providing the information resources and financial management functions. And, FSIS will be responsible for increasing the efficiency of providing the personnel functions. These efficiencies will reduce the cost of recruitment, travel, supplies, printing and reproduction, utilities, automation, program cost accounting, training, rent, and cooperative agreements.

- (e) A decrease of \$260,000 for animal damage control methods development (\$9,681,000 available in FY 1994).

Need for Change. A significant part of APHIS's mission is to protect American agriculture and other resources through identification, demonstration, and application of effective methods that control wildlife and other free-ranging animals; thereby, minimizing their adverse impact on agricultural production, wildlife preservation, and public safety. However, persistent Federal deficits dictate that some APHIS programs must be reduced in order to achieve deficit reduction goals.

A strategic opportunity exists to establish Lincoln University at Jefferson City, Missouri, (an 1890 Land Grant Institution) as the U.S. Department of Agriculture's (USDA) Center of Excellence in Wildlife Management with a focus on improving the University's research and teaching capacities. This initiative would position the University to serve as a continuous source, beginning in FY 1994, for exploring and testing new wildlife management ideas, techniques, and methods and for developing a cadre of highly qualified and culturally diverse wildlife managers from which USDA agencies, other employers, and university graduate programs may recruit.

Nature of Change. Funds will continue to be used to support a program that focuses on maintaining and improving current methods for controlling damage caused by wildlife and other free-ranging animals and to continue to search for alternative methods. APHIS will slow the pace of reregistration of the lower priority vertebrate pesticides.

APHIS will provide \$225,000 to continue developing Lincoln University's capacity as a USDA Center of Excellence. These funds, along with an equal amount of funds from U.S. Forest Service, together with resources from the University, will be used to support this effort.

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Animal and Plant Health Inspection Service
Geographic Breakdown of Obligations and Staff-Years
1993 Actual and Estimated 1994 and 1995

	<u>1993</u>		<u>1994</u>		<u>1995</u>	
	<u>Amount</u>	<u>Staff Years</u>	<u>Amount</u>	<u>Staff Years</u>	<u>Amount</u>	<u>Staff Years</u>
Alabama.....	\$4,033,766	42	\$4,161,364	42	\$4,017,413	42
Alaska.....	333,506	5	344,055	5	332,154	5
Arizona.....	10,315,081	84	10,641,373	84	10,273,262	84
Arkansas.....	2,412,891	63	2,489,217	63	2,403,109	63
California....	35,911,762	469	28,408,005	467	27,425,305	469
Colorado.....	10,123,264	283	10,443,488	281	10,082,223	281
Connecticut...	469,687	10	484,544	10	467,783	10
Delaware.....	400,407	6	413,073	6	398,784	6
Florida.....	14,020,445	337	14,463,946	335	13,963,604	336
Georgia.....	5,085,499	61	5,246,366	61	5,064,881	61
Hawaii.....	12,553,727	213	12,950,832	212	12,502,832	213
Idaho.....	3,144,884	44	3,244,364	44	3,132,134	44
Illinois.....	2,135,800	41	2,203,361	41	2,127,141	41
Indiana.....	1,382,814	28	1,426,556	27	1,377,208	28
Iowa.....	20,493,433	53	21,141,691	53	20,410,350	53
Kansas.....	1,641,991	38	1,693,931	38	1,635,334	38
Kentucky.....	1,924,064	46	1,984,927	46	1,916,263	46
Louisiana.....	4,576,138	74	4,720,893	73	4,557,586	74
Maine.....	710,796	15	733,280	15	707,914	15
Maryland.....	71,782,391	820	74,053,045	817	71,491,374	819
Massachusetts.	2,492,626	48	2,571,474	48	2,482,520	48
Michigan.....	4,564,275	74	4,708,654	74	4,545,770	74
Minnesota.....	31,956,205	208	32,967,059	208	31,826,650	208
Mississippi...	5,888,435	105	6,074,701	105	5,864,562	105
Missouri.....	2,320,452	44	2,393,853	44	2,311,044	44
Montana.....	3,025,340	58	3,121,039	58	3,013,075	58
Nebraska.....	2,379,842	36	2,455,122	36	2,370,194	36
Nevada.....	1,240,868	24	1,280,120	24	1,235,837	24
New Hampshire.	382,998	9	395,113	8	381,445	9
New Jersey....	6,246,794	110	6,444,396	110	6,221,469	110
New Mexico....	2,423,511	54	2,500,173	54	2,413,686	54
New York.....	9,203,526	208	9,494,656	207	9,166,214	208
North Carolina.....	6,876,638	116	7,094,163	115	6,848,759	116
North Dakota..	2,075,840	26	2,141,504	26	2,067,424	26

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	1993		1994		1995	
	<u>Amount</u>	<u>Staff Years</u>	<u>Amount</u>	<u>Staff Years</u>	<u>Amount</u>	<u>Staff Years</u>
Ohio.....	1,724,320	28	1,778,864	28	1,717,329	28
Oklahoma.....	3,086,629	62	3,184,267	62	3,074,116	62
Oregon.....	3,465,923	55	2,890,177	55	2,790,199	55
Pennsylvania..	4,088,518	59	4,217,848	59	4,071,943	59
Rhode Island..	192,255	3	198,337	3	191,476	3
South Carolina.....	4,576,992	57	4,721,773	56	4,558,436	56
South Dakota..	1,259,256	21	1,299,089	21	1,254,151	21
Tennessee.....	3,237,035	70	3,339,430	70	3,223,911	70
Texas.....	33,878,627	587	34,950,292	583	33,741,278	583
Utah.....	2,486,929	33	2,565,597	33	2,476,847	33
Vermont.....	417,098	10	430,292	10	415,407	10
Virginia.....	1,631,254	31	1,682,855	31	1,624,641	31
Washington....	4,823,180	68	4,290,368	68	4,141,954	68
West Virginia.	714,045	14	736,632	14	711,151	14
Wisconsin.....	2,593,326	67	2,675,360	67	2,582,813	67
Wyoming.....	1,673,813	41	1,726,759	41	1,667,027	41
Wash., DC.....	41,203,055	436	42,506,410	434	41,036,012	435
Puerto Rico...	17,553,632	209	6,941,475	209	6,701,353	209
Virgin Islands.....	306,689	6	316,391	6	305,446	6
Asia/Pacific..	1,056,102	8	1,089,509	8	1,051,820	8
Bahamas.....	506,426	4	522,446	4	504,373	4
Central America.....	7,720,513	15	7,964,732	15	7,689,213	15
Chile.....	274,124	11	282,795	11	273,013	11
Colombia.....	1,750,359	3	1,805,727	3	1,743,263	3
Dominican Republic.....	283,703	4	292,677	4	282,553	4
Europe/Africa.	1,258,639	13	1,298,453	13	1,253,536	13
Guam.....	6,498	0	6,704	0	6,472	0
Guatemala....	2,725,620	15	2,811,838	15	2,714,570	15
Mexico.....	28,747,072	181	29,656,413	181	28,630,527	182
Panama.....	613,960	2	633,381	2	611,471	2
Venezuela.....	318,688	4	328,771	4	317,396	4
Total, available or estimate.....	\$458,703,976	5,969	\$452,036,000	5,947	\$436,399,000	5,960

NOTE: Total staff-years for 1993, 1994, and 1995 are 6,389, 6,470, and 6,400 respectively when staff-years for miscellaneous trust funds and reimbursements are included.

Proposed Functional Line Item Structure

The Animal and Plant Health Inspection Service (APHIS) proposes to establish a new budget line-item structure for plant health activities that more accurately describes funding based on the actual functions performed. Currently, line items represent either a specific plant pest, a pest prevention or control program, or technical support (i.e., methods development). The proposed functional budget would provide for consistent pest exclusion, survey and monitoring, and scientific and technical services without direct links to traditional plant pest control programs. The structure would allow for continued survey and monitoring after pest eradication activities are completed. This budget restructure is similar to the restructure of animal health activities that become effective in Fiscal Year 1994.

The proposed functional budget would restructure 16 of the current line items into 5 functional line items as follows:

- The plant pest survey line item will combine the current fruit fly detection, grasshopper annual appropriations for surveys, miscellaneous plant pests, honey bee pests, imported fire ant, and plant pest detection program line items; plus the survey and monitoring portions of the gypsy moth, noxious weeds, pink bollworm, and witchweed program line items.

The plant pest surveys will provide early detection of exotic plant pests to prevent sustained infestations and will monitor the effectiveness of plant pest management programs. The objectives are to conduct surveys that will effectively detect new infestations of exotic pests before they become established; to fully support post-eradication activities to maintain program accomplishments; and to facilitate the entry of U.S. agricultural products into international markets.

- The biological control line item will include the field delivery portion of the current biocontrol and Russian wheat aphid program line items. This is the operational portion of these programs and should remain separate from the methods development activities.
- The plant pest management line item will include the current golden nematode, Mediterranean fruit fly, and Mexican fruit fly program line items; and the regulatory and control portions of the gypsy moth, noxious weeds, and pink bollworm program line items.

The plant pest management line item will compliment the current boll weevil and grasshopper control and/or regulatory activities necessary to eliminate or restrict the economic and environmental damage caused by plant pests. The objectives of regulatory activities are to perform certification inspections of regulated articles and to conduct public information/education activities to prevent the spread of plant pests through artificial movement. The objectives of control activities will be to support pest management, suppression, and/or eradication programs to reduce or eliminate the economic impact of a pest utilizing the most effective and environmentally acceptable control strategy.

- The witchweed eradication line item will include the eradication portion of the current witchweed program line item. The eradication aspect of this program is short-term and should remain separate from the survey aspect of the program which is an ongoing activity and continues after eradication activities are shifted to the States.
- The plant program methods development line item will include the current plant methods program line item and the scientific and technical portions of the biocontrol and Russian wheat aphid program line items.

The plant program methods development line item will develop and advance new and existing operational technologies for plant pest exclusion, detection, suppression, and control for APHIS and its stakeholders in a cooperative effort with Federal and State agencies. The objectives are to develop technically sound management systems to support rearing facilities, to develop experimental systems and conduct field trials that allow for comparison of technologies for controlling unwanted pests and diseases.

Attached are crosswalk tables for 1993 to FY 1995. Also attached is a project statement which shows how the new line items would be used to represent the APHIS budget.

Proposed Line Item Structure FY 1993 Crosswalk Table (Actual Dollars)						
Current Program Name	FY 1993 Current	Plant Pest Survey	Biological Control	Plant Pest Management	Witchweed Eradication	Plant Program Methods Dev.
PEST & DISEASE EXCLUSION						
Mediterranean fruit fly	10,424,824			(10,424,824)		
Mexican fruit fly	2,137,046			(2,137,046)		
PLANT AND ANIMAL HEALTH MONITORING						
Fruit Fly Det.	3,233,202	(3,233,202)				
Pest Detection	4,281,942	(4,281,942)				
PEST AND DISEASE MANAGEMENT						
Biocontrol	5,038,081		(1,712,948)	(644,036)		(3,325,133)
Golden Nematode	644,036					
Grasshopper	3,178,814	(3,178,814)				
Gypsy Moth	4,479,802	(1,567,931)		(2,911,871)		
Honeybee Pests	283,255	(283,255)				
Imported Fire Ant	3,475,158	(3,475,158)				
Misc. Plant Pests	2,135,211	(2,135,211)				
Noxious Weed	637,862	(31,893)		(605,969)		
Pink Bollworm	2,870,127	(1,291,557)		(1,578,570)		
Russian Wheat Aphid	1,920,104		(652,835)			(1,267,269)
Sweet Potato Whitefly	2,583,022		(1,214,021)			(1,369,001)
Witchweed	5,588,081	(1,768,186)			(3,799,895)	
SCIENTIFIC AND TECHNICAL SERVICES						
Plant Methods	5,191,236					(5,191,236)
TOTAL	58,101,803	21,267,149	3,579,864	18,302,316	3,799,895	11,152,639

Proposed Line Item Structure FY 1994 Crosswalk Table (\$ in Thousands)						
Current Program Name	FY 1994 Current	Plant Pest Survey	Control Biological	Plant Pest Management	Witchweed Eradication	Plant Program Methods Dev.
PEST & DISEASE EXCLUSION						
Mediterranean Fruit Fly	10,199			(10,199)		
Northeastern Fruit Fly	2,272			(2,272)		
PLANT AND ANIMAL HEALTH MONITORING						
Fruit Fly Det.	3,993	(3,993)				
Pest Detection	3,444	(3,444)				
PEST AND DISEASE MANAGEMENT						
Biocontrol	5,762		(1,539)			(3,763)
Golden Nematoide	698			(698)		
* Grasshopper Reserve	0	0				
Gypsy Moth	5,209	(1,827)		(3,382)		
Nonnative Pests	390	(390)				
Imported Fire Ant	2,700	(2,700)				
Misc. Plant Pests	1,995	(1,995)				
Northern Weed	478	(24)		(451)		
Pink Boleworm	2,282	(1,031)		(1,251)		
Quacken Wheat Aphid	2,400		(819)			(1,584)
Sweet Potato Whitefly	3,514		(1,723)		(2,775)	(1,792)
Witchweed	4,061	(1,309)				
SCIENTIFIC AND TECHNICAL SERVICES						
Plant Methods	5,084					(5,084)
TOTAL	24,350	10,683	4,477	18,223	2,775	12,223

* In FY 1994, all grasshopper activities will be funded through the carryover in the grasshopper reserve no-year account, thus there are no new appropriated funds shown.

Proposed Line Item Structure FY 1995 Crosswalk Table (\$ in Thousands) (Estimate)						
Current Program Name	FY 1995 Current	Plant Pest Survey	Biological Control	Plant Pest Management	Witchweed Eradication	Plant Program Methods Dev.
PEST & DISEASE EXCLUSION						
Mediterranean fruit fly	10,089			(10,089)		
Mexican fruit fly	2,156			(2,156)		
PLANT AND ANIMAL HEALTH MONITORING						
Fruit Fly Det	3,923	(3,923)				
Pest Detection	4,208	(4,208)				
PEST AND DISEASE MANAGEMENT						
Biocontrol	7,754		(2,636)	(615)		(5,118)
Golden Nematode	615	0				
* Grasshopper Reserve	0					
Gypsy Moth	5,177	(1,612)		(3,365)		
Honeybee Pests	0	0				
Imported Fire Ant	0	0				
Misc. Plant Pests	1,986	(1,888)		(384)		
Noxious Weed	404	(20)				
Pink Bollworm	1,069	(481)	0	(588)		0
Russian Wheat Aphid	0					0
Sweet Potato Whitefly	0					0
Witchweed	1,975	(632)			(1,343)	
SCIENTIFIC AND TECHNICAL SERVICES						
Plant Methods	5,059					(5,059)
TOTAL	44,415	13,082	2,636	17,187	1,343	10,177

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PROPOSED LINE ITEM STRUCTURE

PROJECT STATEMENT
(On Basis of Appropriation)

Project	1993 Actual		1994 Estimated		Increase or Decrease	1995 Estimated	
	Amount	Staff- Years	Amount	Staff- Years		Amount	Staff- Years
1. Pest and disease exclusion:							
(a) Agricultural quarantine inspection (Appropriated)...	\$23,742,021	546	\$24,246,000	600	\$894,000	\$25,140,000	618
(b) Agricultural quarantine inspection (User fees).....	83,362,000	1,529	91,460,000	1,604	10,400,000	101,860,000	1,838
(c) Foot-and-mouth disease.....	4,226,198	10	4,046,000	11	-51,000	3,995,000	10
(d) Import-Export inspection.....	11,163,785	148	6,800,000	91	-265,000	6,535,000	89
(e) International programs.....	4,366,211	46	5,826,000	50	280,000	6,106,000	49
(f) Screwworm.....	31,167,301	87	34,645,000	91	-616,000	34,029,000	82
Total, Pest and Disease Exclusion.....	158,027,516	2,366	167,023,000	2,447	10,642,000	177,665,000	2,686
2. Plant and animal health monitoring:							
(a) Animal health monitoring & surveillance.....	59,378,000	636	59,933,000	657	-552,000	59,381,000	643
(b) Animal and plant health regulatory enforcement.....	5,623,823	125	5,849,000	129	16,000	5,865,000	117
(c) Plant pest survey.....	21,267,149	287	16,652,000	261	-3,590,000	13,062,000	221
Total, Plant and animal health monitoring.....	86,268,972	1,048	82,434,000	1,047	-4,126,000	78,308,000	981
3. Pest and disease management:							
(a) Animal damage control operations.....	25,568,147	511	26,092,000	525	-2,661,000	23,431,000	482
(b) Aquaculture.....	-	-	-	-	493,000	493,000	6
(c) Biological control.....	3,579,804	58	4,477,000	66	-1,841,000	2,636,000	42
(d) Boll weevil.....	10,089,239	100	13,226,000	95	-142,000	13,084,000	96
(e) Brucellosis.....	30,356,655	277	31,004,000	255	-5,252,000	25,752,000	197
(f) Cattle ticks.....	6,216,057	133	4,597,000	135	-19,000	4,578,000	104
(g) Grasshopper and Mormon cricket: no-year.....	3,292,460	-	-	-	-	-	-
(h) Plant pest management.....	18,302,316	215	18,223,000	191	-1,026,000	17,197,000	180
(i) Preharvest pathogen reduction.....	-	-	-	-	5,702,000	5,702,000	54
(j) Pseudorabies.....	3,678,046	48	4,543,000	33	-1,126,000	3,417,000	40
(k) Salmonella enteritidis.....	2,698,747	48	3,411,000	48	-27,000	3,384,000	41
(l) Scrapie.....	746,851	13	3,000,000	32	-31,000	2,969,000	25
(m) Tropical bont tick.....	-	-	-	-	537,000	537,000	3
(n) Tuberculosis.....	3,933,216	52	5,538,000	56	-39,000	5,499,000	60
(o) Witchweed eradication.....	3,799,895	40	2,775,000	22	-1,432,000	1,343,000	12
Total, Pest and disease management.....	112,261,433	1,495	116,886,000	1,458	-6,864,000	110,022,000	1,342
4. Animal care:							
(a) Animal welfare.....	9,414,220	172	9,262,000	177	-59,000	9,203,000	171
(b) Horse protection.....	382,191	7	481,000	6	-119,000	362,000	6
Total, Animal care.....	9,796,411	179	9,743,000	183	-178,000	9,565,000	177
5. Scientific and technical services:							
(a) Animal control methods development.....	9,551,637	122	9,681,000	125	-329,000	9,352,000	119
(b) Biotechnology environmental protection.....	7,685,841	91	7,756,000	92	-66,000	7,690,000	98
(c) Integrated systems acquisition project.....	2,098,798	5	3,500,000	17	-	3,500,000	17
(d) Plant program methods development.....	11,152,639	200	12,223,000	214	-2,046,000	10,177,000	187
(e) Veterinary biologics.....	9,772,190	181	10,434,000	191	-63,000	10,371,000	184
(f) Veterinary diagnostics.....	14,285,314	169	14,946,000	173	-135,000	14,811,000	169
Total, Scientific and technical services.....	54,546,419	768	58,540,000	812	-2,639,000	55,901,000	774

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Project	1993 Actual		1994 Estimated		Increase or Decrease	1995 Estimated	
	Amount	Staff- Years	Amount	Staff- Years		Amount	Staff- Years
6. Contingencies: plant and animal diseases and pests.....	5,838,672	--	4,938,000	--	--	4,938,000	--
7. Transfer to the Office of the Secretary.....	-212,000	--	--	--	--	--	--
Unobligated balance available start-of-year.....	-22,731,000	--	--	--	--	--	--
Unobligated balance available end-of-year.....	35,663,000	--	--	--	--	--	--
Unobligated balance expiring.....	1,086,000	--	--	--	--	--	--
Total, Available or estimate, salaries and expenses.....	440,545,323	5,856	439,564,000	5,947	-3,165,000	436,399,000	5,960
8. CCC transfer (fruit fly and Asian gypsy moth).....	16,094,304	115	--	--	--	--	--
9. From FNS for cattle tick.....	10,825,000	--	12,472,000	--	-12,472,000	--	--
10. Advances and Reimbursements:							
(a) Federal.....	8,264,406	68	7,956,000	67	-147,000	7,809,000	64
(b) Non-Federal.....	25,986,572	299	29,486,000	403	2,248,000	31,734,000	323
Total, Advances and Reimbursements.....	34,250,978	367	37,442,000	470	2,101,000	39,543,000	387
Total, Available or estimate.....	501,715,605	6,338	489,478,000	6,417	-13,536,000	475,942,000	6,347

No-Year and Emergency Programs

Project	1993 Actual	1994 Carry-Over	1994 Appropriated	1994 Available
Animal Damage Control..	5,988,955	900,842	--	900,842
Boll weevil.....	10,089,239	3,045,761	13,226,000	16,271,761
Grasshopper/Mormon				
Cricket reserve fund.....	3,292,460	13,267,552	--	13,267,552
10% of Screw-worm.....	2,437,852	1,026,648	3,465,000	4,491,648
Contingency Fund.....	5,838,671	2,086,662	4,938,000	7,024,662
Fruit flies.....	13,476,983	12,530,471	--	12,530,471
Asian Gypsy Moth.....	1,328,733	739,918	--	739,918
ISAP.....	2,098,817	1,837,189	3,500,000	5,337,189
Total.....	44,551,710	35,435,043	25,129,000	60,564,043

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ANIMAL AND PLANT HEALTH INSPECTION SERVICE

SALARIES AND EXPENSES

STATUS OF PROGRAM

PEST AND DISEASE EXCLUSION

Current Activities: The Animal and Plant Health Inspection Service (APHIS) conducts agricultural inspections and international pest and disease programs, to prevent exotic plant and animal pests and diseases from entering the United States. Preventing the entry of exotic pests and diseases is increasingly challenging in the expanding global environment. International travel continues to increase. International trade has also increased, as a growing number of traditional and non-traditional agricultural products are imported and exported. The accelerating international activity increases the risk that pests and diseases will spread. Each person, bag, and import or export commodity could carry a pest or disease capable of causing a major outbreak. APHIS continues to conduct successful international control and eradication programs, and has expanded the number of items it monitors. Specific program efforts through which the Agency defends U.S. agriculture from pest and disease introductions are:

Inspection along U.S. borders and at ports-of-entry. Along with manual inspections, the Agency is exploring and utilizing alternative inspection methods and technologies. Each year, APHIS performs more inspections with X-ray systems and detector dogs. The use of new technologies has improved the overall efficiency and effectiveness of inspections.

Inspection of imported and exported animals. The Agency ensures that all exported livestock, live poultry, hatching eggs, bovine semen, and bovine embryos have been inspected and certified free from contagious diseases. Exports must also comply with health agreements between the U.S. Department of Agriculture (USDA) and importing countries. The Agency routinely meets with international agricultural health officials to facilitate international trade by clarifying and amending import requirements, as necessary.

Eradication and control of pests and diseases in foreign countries. The Agency combats pests and diseases in foreign countries, thus reducing their threat to the United States. APHIS works with international agricultural groups to keep Mexico and Central America free of foot-and-mouth disease and other exotic animal disease; to continue screwworm eradication through Central America; to eradicate Mediterranean fruit flies (Medfly) from Guatemala; and to prevent Mexican fruit flies (MFF) from infesting northwestern Mexico.

Selected Examples of Recent Progress:1. Agricultural Quarantine Inspection (AQI)

In Fiscal Year (FY) 1993, 47 million passengers arrived at U.S. ports, an increase of almost 7 million over FY 1992. Passenger arrivals are projected to steadily increase to the year 2000. APHIS continued to work with the U.S. Customs Service to expedite the clearance of passengers while maintaining adequate protection for American agriculture. In addition, 1,799,729 passengers were precleared and

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29,273 contraband interceptions were made for the Bahamas and Bermuda. Preclearance at domestic and overseas locations provides a high level of protection to U.S. agriculture. These activities help to protect the multi-billion dollar agriculture industry.

A military preclearance program was successfully completed in Somalia following Operation Restore Hope. Due to downsizing of military there has been a significant increase in the supervisory workload in areas such as Japan, Korea, and Europe. Road station vehicle inspection activities in northern Mexico continued and were effective in reducing the risk of fruit fly infested fruit from being introduced in fly-free areas of the United States. A total of 132 metric tons of contraband materials were treated or destroyed.

APHIS continued to use specially trained dogs to detect prohibited items at international airports. In FY 1993, APHIS maintained 33 detector dog teams located at 17 major airports and post offices in the United States. Honolulu, Los Angeles, and San Francisco post offices have dog teams. Within the next 2 years, we plan to expand the program to 60 teams.

The Agency continued using X-ray equipment as a screening tool in passenger baggage clearance. Currently, APHIS uses 74 X-ray machines at major airports and land border stations. The clearance units are located at 17 foreign-arrival sites and 8 departure sites. They include: San Juan (10), Miami (3), Hawaii (31), Chicago (2), JFK/New York (4), Houston (2), Boston (1), Atlanta (1), Dulles/Washington, DC area (1), Los Angeles (4), San Francisco (2), Elizabeth, New Jersey (2), Seattle-Tacoma (1), Dallas (2), San Jose (1), Orlando (1), San Ysidro (2), Hoboken, New Jersey (1), Roosevelt Road Navy (1), Mayaguez (1), and Ponce (1).

Air passenger baggage inspections continued at an increased level at the Tijuana Airport in Mexico, where 14.8 metric tons of quarantine materials were intercepted. A total of 2,818 live Mexican fruit fly larvae were intercepted from these products. One road station operation was turned over to Mexican counterparts.

APHIS uses its civil penalty authority for inadequate notice of arrivals, passenger baggage violations, and maritime garbage violations. In FY 1993, APHIS collected about \$1.54 million in violations, assessing approximately 27,900 civil penalties. In addition, the Agency inspects cargo and carriers entering the United States. APHIS conducted inspections of about 45,000 ships and 919,349 regulated and miscellaneous cargo this fiscal year.

EXCERPT is a computerized database that contains up-to-date export summaries used for issuing phytosanitary certificates. With a personal computer and modem, users will be able to access a remote host computer to retrieve export summaries of more than 50 countries. Development, testing, and initial training of trainers for EXCERPT are complete. Beginning in February 1993, approximately 25 PPQ and National Plant Board sites from across the nation were brought on-line each month, with over 400 users by the end of October 1993. The FY 1994 work plan for EXCERPT calls for continued implementation nationwide.

During FY 1993, APHIS investigated 144 complaints of possible violations to plant health regulations. Also, 980 formal cases were initiated as a result of the findings of investigated complaints. The Agency issued 46 warnings and forwarded 190 cases to the Office of the General Counsel for final disposition.

The Farm, Agriculture, Conservation and Trade (FACT) Act, as amended by the Omnibus Budget Reconciliation Act of 1990, authorized APHIS to collect user fees for AQI services. On May 13, 1991, APHIS implemented fees for international aircraft passenger inspections and loaded boxcars. On July 1, 1991, APHIS implemented fees for inspections of commercial vessels and commercial trucks. User fees for export certification were implemented during FY 1992. The Agency collected an estimated total of \$100.9 million in FY 1993. Since the implementation of user fees, APHIS has saved taxpayers \$239.3 million.

2. Foot-and-Mouth Disease (FMD)

Panama and Central America

APHIS, in cooperation with animal health officials and other international organizations such as the International Regional Agricultural Health Organization, the Pan American Health Organization, and the Inter-American Institute for Cooperation in Agriculture, has continued to prevent FMD from entering the United States, Mexico, Panama, and Central America.

The Panama program conducted active FMD field surveillance in the border area adjacent to Colombia in support of the FMD-free status in Panama. APHIS continued to provide support for the Vesicular Disease Diagnostic Laboratory in Panama City, Panama, to ensure reliable and timely diagnostic capabilities for FMD detection throughout Central America. During FY 1993, over 350 Central American FMD-suspect biological specimens were processed at this laboratory. None of these specimens tested positive for FMD. However, numerous specimens tested positive for vesicular stomatitis, a disease clinically indistinguishable from FMD.

Colombia

In Colombia, APHIS provided financial and technical assistance to the cooperative Colombian Agriculture Institute and USDA's 50/50 cost sharing FMD control program. The program continued to maintain the FMD-free area in Colombia, contiguous with and southeast of the border with Panama. Success of this program can be measured by the gradual increase in the FMD-free areas in Colombia. This expanded area results in increased protection to Panama, Central America, Mexico, and the United States.

Mexico

APHIS continued its successful exclusion of FMD and other foreign animal diseases (FAD) in Mexico through the support of the joint Exotic Animal Disease Commission (EADC). EADC efforts are principally dedicated to: surveillance and outbreak investigations for prevention of FAD entering Mexico; diagnostic capabilities for rapid detection of FAD throughout Mexico; and training and public education to communicate animal disease prevention measures.

During FY 1993, there were 649 FAD investigations, 2,102 screwworm investigations, and 770 investigations for viral hemorrhagic disease of rabbits. Of the 396 cases of reportable diseases diagnosed by the EADC high containment laboratory, 78 were for vesicular investigations. Large increases in diagnosed cases of swine systemic diseases and equine neurologic diseases were observed in FY 1993.

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Significant events occurring during FY 1993 included the identification of five screwworm cases in Veracruz and Tlaxmalipas during May and June, respectively. Over 100,000 ranch visits were made during this emergency operation. In May, an outbreak of hog cholera was detected in Baja California Sur. Approximately 3,500 premises were visited, with a total of 2,062 animals sacrificed. The 116 necropsies completed in the field produced 150 samples sent to and processed at the EADC laboratory. In June 1993, the first case since 1972 of Venezuelan equine encephalomyelitis was reported in Chiapas, Mexico. A total of 158 field investigations were made and approximately 35,000 horses were vaccinated.

3. Import/Export Inspection

Import Animals

Two animal importations were conducted at the Harry S Truman Animal Import Center (HSTAIC) in FY 1993. The first, in October 1992, consisted of 102 breeding swine from Germany. These swine had negative results on tests for FMD, hog cholera (HC), and other swine diseases. They were released in January 1993. The second importation, in September 1993, consisted of 425 alpacas and llamas from Peru. Also in FY 1993, several thousand straws of bovine semen were imported from Brazil, a country where FMD exists. APHIS supervised the testing of the 26 bulls as well as the semen collection and processing.

In July 1993, a regulation was published that requires a 7-day vector-free quarantine period for imported horses from Mexico. This regulation was needed because of the outbreak of Venezuelan equine encephalitis in Chiapas, Mexico. APHIS veterinarians met with Mexican counterparts several times in FY 1993 to address animal health issues affecting the import and export of cattle, other ruminants, poultry, and equine and their products. Also in FY 1993, approximately 50,000 heifers were spayed by U.S. and Mexican veterinarians under APHIS supervision.

APHIS initiated regulation changes and developed protocols for the importation of sheep and goats and their embryos and semen. In addition, the Agency drafted protocols and regulations for the importation of cattle, sheep, and goat embryos from Africa, and wild ruminant semen from Thailand, Kenya, and Nepal. Protocols were also written for the importation of swine from Australia and Ireland and bovine semen from Ireland. Also in FY 1993, APHIS published proposed regulations concerning the importation of semen and embryos, the importation of ruminants and swine from FMD countries through the HSTAIC, and the removal of quarantine requirements in HSTAIC for the importation of camelids from Chile.

Boer goat embryos and 10 live goats were imported from Australia for research in FY 1993. The animals resulting from the embryos are quarantined for scrapie until 1995. Twenty-three Bactrain camels were refused entry because of caudal-fold responses to the tuberculin test. Mycobacteriosis was diagnosed and the animals were euthanized, because the importer could not find another country that would accept the animals.

Also in FY 1993, APHIS met with officials of the 1996 Olympic Games to develop quarantine and test requirements for the importation of horses into Atlanta, Georgia.

Export Animals

In FY 1993, APHIS negotiated with several countries to establish or update animal health protocols for the exportation of U.S. origin animals, semen, and embryos. Countries whose protocols were updated or revised included Algeria, Argentina, Bahrain, Brazil, Canada, Chile, Egypt, the European Community (EC), Israel, Jamaica, Japan, Korea, Mexico, New Zealand, Poland, Senegal, South Africa, Sweden, the Russian Federation, Taiwan, Thailand, Ukraine, and Zimbabwe. APHIS continued to participate in the U.S./Mexico Animal Health Working Group to discuss changes in import health requirements for each country and in the Canada/U.S. Trade Agreement (CUSTA) Technical Working Group meetings with Agriculture Canada. In addition, the Agency participated in a U.S./Mexico border port meeting to establish uniform import and export procedures for the U.S./Mexico border. APHIS also met with EC Member State representatives to discuss horse movements between the U.S. and the EC.

Among several diseases that affected the U.S. export market in FY 1993, porcine reproductive and respiratory syndrome (PRRS) had the most significant impact. Many countries restricted the importation of live swine, porcine semen, and pork due to PRRS occurrence in the United States. The most recent example of these restrictions occurred in Venezuela, where a total ban was imposed on the importation of swine and pork from countries with PRRS. USDA's routine avian influenza (AI) surveillance and the reported finding of non-pathogenic strains of the virus in the Northeast caused several Latin American countries to restrict the importation of day-old chicks, hatching eggs, and poultry meat. Also in FY 1993, the poultry industry invited veterinary officials from Colombia and Venezuela to observe the distinction between commercial poultry and backyard flocks. To date, only Venezuela continues to maintain a total ban on U.S.-origin poultry because of AI.

Animal Products

APHIS recognized France, New Caledonia, Spain, and The Netherlands as being free of FMD and Spain free of HC. In September 1993, a proposed regulation was published in the Federal Register to recognize Belgium as being free of FMD and the Agency conducted an onsite evaluation of the FMD situation in Germany. Also, APHIS withdrew recognition of Spain as free of swine vesicular disease (SVD) because of a March 1993 outbreak. SVD presence will delay approval by APHIS to allow the importation of certain cured and dried hams from Spain into the United States. During the year, APHIS issued 6,370 permits authorizing the importation of organisms, vectors, biological materials, and animal products and byproducts. This was an increase of 489 permits over the number issued in FY 1992. Anticipating the move towards regionalization, APHIS began developing strategies for evaluating and recognizing disease free areas. These include standards for assessing and analyzing risk factors that are critical to verifying and maintaining disease-free areas. Also in FY 1993, APHIS published a proposed regulation to allow the importation of cooked beef patties from FMD-affected countries.

4. International Programs

Foreign Disease and Pest Exclusion

APHIS veterinarians and plant health specialists worked closely with foreign governments and industry, particularly in Mexico, Central and South America, including the Andean countries, Italy, Kenya, Haiti, Japan, Taiwan, Korea, Australia, and New Zealand, to protect American

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Agriculture. APHIS personnel also ensured the biological safety of animals, plants, and agricultural products coming into the United States through inspection and certification of foreign facilities, carriers and cargoes.

APHIS continued to conduct preclearance inspections of fruits, vegetables, and a limited amount of propagative material in 21 countries worldwide: Belgium, England, Ireland, Netherlands, Israel, Turkey, Spain, South Africa, Ecuador, Peru, Brazil, Venezuela, Mexico, Guatemala, South Korea, Japan, New Zealand, Australia, Chile, Argentina, and Haiti. Commodity preclearance overseas provides the United States with additional protection against the introduction of plant pests and diseases by detecting and eliminating pests at their origin.

FY 1993 preclearance activities in Chile, a major supplier of winter fruits and vegetables to the United States, remained stable at about 60 million cartons. APHIS has increased its activities with the Dutch bulb program, from preclearing 454,520,825 flower bulbs in 1973, to over 1 billion bulbs in 1993. These flower bulbs were destined to the United States for fall planting. Preclearance programs for mangos subject to hot water dip treatment continued in Mexico, Haiti, Brazil, Venezuela, Peru, and Ecuador. Imports are expected to increase with the opening of a new export facility, Nova Fronteira in Brazil, at the end of FY 1993.

Export Facilitation

The Agency has increased its efforts in the facilitation of U.S. agricultural exports worldwide through bilateral discussions with several countries including Japan, Australia, Chile, New Zealand, Korea, and Taiwan. APHIS participated in the Uruguay Round of the General Agreement on Trade and Tariffs negotiations and the U.S./EC Working Groups on phytosanitary and sanitary matters, the North American Free Trade Agreement negotiations, and the Mexico/United States working groups on phytosanitary and sanitary issues. In support of this, APHIS attaches stationed abroad increased their efforts and activities in identifying, negotiating, and eliminating technical zoosanitary and phytosanitary trade barriers that impede U.S. agricultural exports. APHIS increased its representation with the EC during FY 1993, with the establishment of a regional office in Brussels.

APHIS continued preclearance for Japanese and Korean sandpears; Mexican citrus, mangos, and other fruits; and, New Zealand and Australian apples and pears.

In August 1993, the APHIS Trade Support Team (TST) completed its 1-year pilot. This initiative was undertaken in response to the increasing volume and complexity of trade issues facing the Agency. In its first year, the TST achieved the following:

- Assisted the Department and the U.S. Trade Representative (USTR), in resolving commodity disputes with foreign governments over sanitary and phytosanitary issues. Sales of \$120 million in apples and other fruit were preserved, through negotiations with Taiwan.

- Strengthened Department-wide coordination on trade issues. Day-to-day contact and coordination with the Foreign Agricultural Service (FAS) and the USTR on technical trade barrier issues has improved significantly.

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This has helped ensure that APHIS' biosecurity objectives are integrated into the Department's international trade policy goals and negotiations.

- Performed monitoring and analysis of regional and global trade developments. Tracked and coordinated the Department's response to the new sanitary and phytosanitary situation evolving from the implementation of the EC single market plan.

- Served as focal point for inquiries on APHIS trade policies, activities, and other trade-related issues. The TST has provided these informational services to the Secretary's office, Agency field and headquarters personnel, U.S. government agencies, and U.S. industry groups.

- Provided APHIS representation at intradepartmental meetings regarding trade and environmental issues. Assisted in formulating Agency and/or Departmental responses and positions on environmental assessment of trade agreements, biotechnology and trade, and trade assessments of environmental agreements.

- Assisted in Agency and/or Departmental preparation for bilateral meetings and meetings with international organizations such as U.S.-Mexico Binational Commission, North American Plant Protection Organization, Inter-American Institute for Cooperation in Agriculture, Organization for Economic Cooperation and Development.

5. Mediterranean Fruit Fly (Medfly)

APHIS cooperated with the California Department of Food and Agriculture on a Medfly eradication project located in the Los Angeles basin during FY 1993. The 1,000 square-mile quarantine area included portions of Los Angeles, Orange, and San Bernardino Counties.

In FY 1993, APHIS' sterile Medfly rearing facility in Waimanalo, Hawaii, produced more than 18.4 billion sterile flies. More than 14 billion of these went to California for use in Medfly eradication projects. The facility is currently producing 300 million sterile flies per week for California eradication efforts. APHIS provided 1.5 billion sterile flies together with sterile release equipment to the Agricultural Research Service (ARS) in support of its Kauai eradication test. This test has now been completed, and APHIS currently provides small amounts of pupae on an as-needed basis for follow-up studies. APHIS and ARS also updated the National ARS Fruit Fly Research Plan to ensure that research supports current program needs. In addition, Agency support continues in order to maintain the Caribbean Fruit Fly Export Protocol.

APHIS continued efforts to prevent the northward spread of Medfly into northern Guatemala and southern Mexico through a cooperative 50/50 cost sharing program with Mexico and a cooperative program with Guatemala. Medfly populations increased significantly in southwestern Guatemala during FY 1993, resulting in increased outbreaks in southern Mexico. There were 119 Medfly detection sites reported in Mexico in 1993, some as far as 125 miles from the Guatemalan border. This situation compares with 25 detection sites in 1991 and 214 in 1992.

APHIS maintains a network of approximately 4,000 Medfly traps in Mexico to detect outbreaks that would threaten the United States. Also, APHIS and ARS scientists reviewed the Medfly rearing labs in Mexico and Guatemala and made suggestions that have improved the quality of the sterile flies produced there.

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In other developments, APHIS initiated a pilot program to deploy a temperature sensitive lethal strain of sterile Medfly in Guatemala. Females can be eliminated from this strain in the egg stage, allowing for the production and release of only sterile males. The new strain will be available for field trials in FY 1994.

A single Medfly outbreak occurred in Belize in FY 1993, but was successfully eradicated. APHIS' direct oversight during the eradication effort allowed the papaya export program to continue.

6. Mexican Fruit Fly (MFF)

APHIS conducts a survey, regulatory, and control program to prevent the MFF from becoming established in the lower Rio Grande Valley and spreading to other citrus growing areas of the United States. As part of this program, APHIS, the State of Texas, and the citrus industry have developed the MFF protocol, which involves trapping and the release of sterile flies throughout the citrus growing areas of the lower Rio Grande Valley. This protocol enables commercial citrus to be transported out of the valley to other States and abroad, with greatly reduced use of chemical treatments. The program continues to expand as the citrus industry recovers from a freeze which occurred in 1989.

MFF detection and eradication activities are also carried out along the California-Texas-Mexico border, reducing the threat of infestation to California and Texas. This is a cooperative effort involving APHIS, the California Department of Food and Agriculture, and the Mexican plant health organization Sanidad Vegetal.

In FY 1993, APHIS produced over 2.5 billion pupae at the sterile fly rearing facility in Mission, Texas. The capacity of sterile fly production was doubled to meet program needs for eradicating infestations in northwest Mexico and in the State of California. Last year, the Agency released 785 million sterile flies in the LRGV to support the protocol, and is currently releasing approximately 30 million flies per week. In addition, the facility produced approximately 169 million sterile flies for eradication efforts in California and 1.147 billion for suppression and eradication programs in Sonora and northwest Mexico. In addition to sterile fly releases, program activities also include fruit stripping and ground bait applications, depending on MFF detections.

During FY 1993, the dispersion of sterile MFF in Baja California successfully prevented the establishment of MFF in southern California despite the capture of 84 native flies in the Tijuana, Mexico, area. A single MFF outbreak occurred in the Sonora fruit fly free zone, but was eradicated by the emergency response specified in the work plan. APHIS published a plan in the Federal Register to add one municipality to the free zone. APHIS' joint regulatory efforts with the Mexican Secretariat of Agriculture and Water Resources revealed incidents of commercial smuggling of host fruit at road stations and markets in Sonora and Baja California.

7. Screwworm

In FY 1993, APHIS continued to successfully prevent screwworm reintroduction into the United States. Self-sustaining populations of screwworms were eliminated from Mexico, Belize, Guatemala, and El Salvador. Active screwworm eradication continued in Honduras, and

sterile fly dispersal started in Nicaragua. A cooperative agreement was signed with Costa Rica on October 29, 1993, to enable continuation of the program in Central America.

The screwworm sterile fly production facility produced and distributed over 11 billion sterile insects, and field operations collected over 30,000 samples in FY 1993.

An outbreak of screwworm occurred in Mexico in FY 1992, with 61 positive cases having been detected during the fiscal year in five Mexican States. In response to this outbreak, the United States and Mexico initiated an emergency eradication effort involving intensive field surveillance and sterile fly dispersal in the affected areas and neighboring countries. On May 21, 1993, a positive sample was found in the State of Veracruz, Mexico, in an area just outside of the 1992 eradication area. Four additional cases were detected in a small area near the junction of the two Gulf Coast Mexican States of Veracruz and Tamaulipas. The last positive sample in this outbreak was collected on June 17, 1993. If no further positive samples are collected, eradication activities for this outbreak will end in December 1993. The screwworm eradication program cost \$4.3 million during FY 1992 and FY 1993. This unexpected cost delayed the Central America programs by 12 to 24 months.

PLANT AND ANIMAL HEALTH MONITORING

Current activities: APHIS monitors animal and plant health to detect and react to exotic pest and disease introductions. The Agency creates and updates endemic pest and disease information bases and monitors and carries out surveys in cooperation with States and industry. The Agency also surveys for exotic plant pests and investigates reports of suspicious animal pests and diseases. Early detection reduces their spread, helps eliminate significant losses, and helps maintain pest-free status for export certification of agricultural commodities. U.S. agriculture is currently free from hundreds of foreign pest and diseases. Survey data is essential for initiating action programs and results in better pest and disease management.

APHIS works with the States to compile two databases: the National Agricultural Pest Information System (NAPIS) and the National Animal Health Monitoring System (NAHMS). States enter the results of plant pest surveys directly into the NAPIS database, which includes crop hosts, location, weather conditions, pest life stages, crop damage, survey and control methods used on certain pests, and trapping methods. Descriptive data about the occurrence and costs of animal health events are collected from a statistically valid sample of producers for the NAHMS database. NAHMS reports can be used by producers to improve health and production efficiency of livestock and poultry.

Regulatory enforcement activities prevent the spread of communicable animal and plant pests and diseases in interstate trade. These activities include inspection, surveillance, animal identification, and prosecution. The Agency also investigates alleged violations of Federal animal welfare and horse protection laws and regulations and oversees and coordinates subsequent prosecution of violators through appropriate civil or criminal procedures.

The Agency maintains a cadre of trained professionals, prepared to respond immediately to potential animal and plant health emergencies. Reports of suspected exotic pests and diseases are investigated and emergency action is

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taken if necessary. The Agency develops pathway studies and thoroughly investigates the progression of outbreaks to determine the origin of plant and animal pests and diseases.

Selected Examples of Recent Progress:

1. Animal Health Monitoring and Surveillance

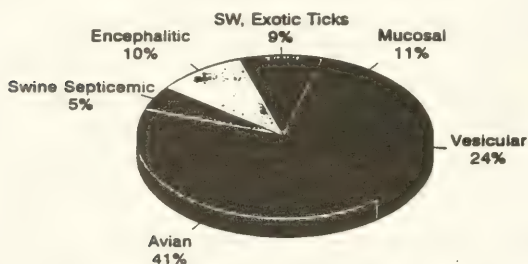
a.) Foreign Animal Disease Investigations

In FY 1993, APHIS conducted 299 investigations for suspected foreign animal diseases (FAD). Seventy-two of these investigations dealt with vesicular conditions, 33 dealt with mucosal disease conditions, 124 dealt with avian diseases, 14 dealt with swine septicemic conditions, 29 dealt with encephalitic conditions, and 27 dealt with screwworm, exotic ticks, or other disease conditions.

FOREIGN ANIMAL DISEASE INVESTIGATIONS			
DISEASE	FY 1991	FY 1992	FY 1993
Vesicular Conditions	102	78	72
Mucosal Conditions	7	17	33
Avian Diseases	58	58	124
Swine Septicemic Conditions	22	11	14
Encephalitic Conditions	34	16	29
Screwworm, Exotic Ticks, other	35	60	27
TOTAL NUMBER OF INVESTIGATIONS	258	240	299

Veterinary Services, Emergency Programs

Foreign Animal Disease Investigations - FY 1993



Total Submissions FY 1993 = 299

APHIS continued its surveillance program for hog cholera and African swine fever by collecting swine blood specimens at slaughterhouses in Maine, Massachusetts, New Hampshire, New Jersey, Arizona, Texas, and Puerto Rico. Additional samples were sent from Arkansas, California, Florida, Hawaii, Illinois, Kentucky, Rhode Island, Vermont, and Washington. The Agency's National Veterinary Services Laboratories (NVSL) in Ames, Iowa, tested 9,035 samples and all were determined to be

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negative for both diseases. APHIS also continued its surveillance program for Velogenic Viscerotropic Newcastle Disease (VVND) and in April 1993, the NVSL isolated the VVND virus from parrots seized from smugglers crossing into the United States. The birds were quarantined and diagnostic samples were collected. Several of these birds died in quarantine. In FY 1993, no VVND outbreaks occurred among caged birds or domestic poultry in the United States. APHIS also continued its Bovine Spongiform Encephalopathy (BSE) surveillance program. In FY 1993, pathologists at NVSL and Iowa State University continued to examine bovine brains from the following sources: 1) FAD investigations where encephalitic conditions in cattle were reported; 2) bovine cases confirmed negative for rabies by the Centers for Disease Control in Atlanta, Georgia; 3) brain specimens collected from slaughterhouses in selected potential high-risk States; and 4) brain tissues submitted by veterinary diagnostic laboratories in the United States.

To enhance the surveillance process, APHIS and the USDA's Food Safety and Inspection Service initiated a pilot project to survey five slaughter plants receiving non-mobile cattle. In addition, Federal and State animal health officials contacted State public health and university diagnostic laboratories to arrange for submission of suspicious specimens to NVSL. Contacts have also been made with private practicing veterinarians to increase reporting rates and submission of brains from suspicious cattle. As of September 30, 1993, 1,215 bovine brains were examined and none contained lesions characteristic of BSE. Also, of the 393 head of traced cattle out of the total of 459 head of cattle imported from the United Kingdom since 1981, none have shown clinical signs of BSE and no BSE cases have been diagnosed in the United States.

In August 1993, APHIS and Agriculture Canada conducted a Regional Emergency Animal Disease Eradication Organizations (READEO) exercise of a simulated FMD outbreak in Montana and Alberta, Canada. An APHIS READEO and the Alberta Regional Emergency Response Team were activated simultaneously with task forces in Montana and Canada. The cattle, swine, and livestock marketing industry were actively involved in the planning and execution of the exercise. This was the first international exercise and the third consecutive exercise that the Agency has conducted to test and strengthen response capabilities to potential outbreaks of emergency animal diseases in the United States. Also in FY 1993, APHIS reviewed and updated its Memoranda of Understanding (MOU) with universities, State laboratories, Federal agencies, and industry to expand the Agency's capability of responding to animal disease emergencies. In addition, a MOU was developed with the American Veterinary Medical Association to establish a reserve cadre of veterinarians and animal health technicians to assist in an animal health emergency. In addition, the USDA-Industry Roundtable met to discuss the enhancement of livestock industry emergency preparedness, the organization of the READEO, and livestock industry interaction within these units.

In FY 1993, APHIS continued to increase FAD awareness and education by conducting two training courses, which provided extensive information on exotic animal diseases in ruminants, equine, and swine. The courses also focused on biosecurity issues, disease investigation techniques, and sample submission procedures. APHIS also participated in a course on the threats posed by FAD's. This course provided specific information on exotic animal diseases, disease control concepts, and the potential economic threat to the U.S. poultry, livestock, and wildlife populations. In addition, the Agency sponsored a workshop to train teachers and veterinary lab diagnosticians on infectious diseases. This

course enhances the awareness of exotic diseases and increases reported rates of specific emergency disease conditions. APHIS also sponsored a wildlife seminar for FAD diagnosticians. This program familiarized participants with wildlife management concepts and reviewed wildlife diseases of North America that have the potential to involve domestic livestock and poultry. In addition, the Agency published three issues of the Foreign Animal Disease Report and distributed them to over 7,000 readers. This report provides FAD updates along with information concerning current emergency preparedness and response activities worldwide.

b.) Miscellaneous Agricultural Monitoring

In FY 1993, the value of proactive animal health monitoring and surveillance was clearly demonstrated by the perceived emergence of a new animal disease, "Weak Calf Syndrome" (WCS), and information needs generated by two human disease outbreaks, E. coli O157:H7 and Cryptosporidium parvum. APHIS responded to a resurgence of WCS, a condition that caused a steep rise in calf deaths in Illinois, Iowa, Missouri, North Dakota, South Dakota, Kansas, and Nebraska. The Agency provided information to the national media on WCS based on beef monitoring data, analysis of data from the National Agricultural Statistics Service, and data from veterinary diagnostic laboratories in the affected States. Scientifically sound, statistically valid information allayed fears and potential public hysteria as the national media spread news on all three of these emerging disease conditions. In addition, the APHIS, NAHMS used data and fecal samples collected in FY 1992 as part of NAHMS dairy monitoring to support outbreak investigations involving (1) E. coli O157:H7 food poisoning cases in Washington and Oregon that led to several human deaths and illness; and (2) Cryptosporidium parvum, a water-borne parasite that infected Milwaukee, Wisconsin's public water supply and led to the illness of an estimated 300,000 residents.

In FY 1993, NAHMS monitored the health and diseases of U.S. beef, dairy, and swine populations. Beef monitoring proceeded with producer interviews and collection of fecal, blood, and forage samples from targeted herds in 18 States with approximately 70 percent of the Nation's beef cow-calf population. Beef producers, industry groups, veterinary practitioner groups, and animal health officials received information on key beef issues including hide branding, vaccination injection sites, and reproductive efficiency. Hide branding is a key factor negatively affecting U.S. export competitiveness. The United States and Canada comprise approximately 43 percent, or \$1.6 billion of the world export market; however, branding on the side or rib decreases the market value of a hide by 16 percent. Swine monitoring included summarizing and reporting monthly trends on the prevalence of Porcine Reproductive and Respiratory Syndrome, a swine disease that Mexico once used as a reason for refusing to buy U.S.-raised hogs. APHIS also used NAHMS expertise to increase the awareness of possible health conditions that could result from the 1993 flooding of the Mississippi River. Potential public and animal health, and regulatory medicine issues were explored in a report that forewarned and assisted animal health officials in areas affected by the flood.

APHIS began feedlot cattle death loss monitoring in FY 1993 and now reports monthly trends in death loss and cause of death in 40 U.S. feedlots, 1.2 million head of cattle, or about 16 percent of the U.S. feedlot cattle population. The Agency is using these trends to plan national feedlot cattle monitoring that will begin in the summer of 1994. In addition, patterns of other diseases in cattle, horses, and

hogs were tracked and reported through the compilation of test results from veterinary diagnostic laboratories in all regions of the United States. Twenty-four laboratories from 22 States now contribute data and expertise, an increase of five laboratories over FY 1992. Domestic and international distribution of reportable diseases provides key disease trend information to over 1,300 diagnosticians, veterinarians, and animal health officials.

Wholesomeness and quality of beef products was also supported through NAHMS beef monitoring analyses of injection practices in the U.S. beef cow/calf industry. Blemishes in beef products caused by injections to the animal decrease consumer confidence that the meat product is wholesome and of high quality. In 1991, beef producers lost \$46 million due to meat that had to be trimmed from the top sirloin butt due to injection practices.

c.) Risk Assessment

APHIS identified and interpreted emerging animal and public health issues using NAHMS risk assessment capabilities and by assessing and analyzing data from multiple sources in addition to NAHMS. Other sources included the National Agricultural Statistics Service; the Centers for Disease Control; the Economic Research Service; and several private information collectors, including Rockwood Research and Doanes Agricultural Information. APHIS analyzed how previous risk factors for BSE have changed since APHIS first analyzed BSE risk for the United States. All risk factors analyzed show either no change since 1991 or a decrease in magnitude, suggesting a decline in BSE risk. APHIS initiated a risk assessment of swine feeding practices, including the disease risks potentially caused by feeding recycled commodities to hogs. Also, the Agency assessed and reported on bovine tuberculosis risk factors, including the importation of Mexican cattle and dramatic growth of the captive Cervidae industry, especially elk and deer, in the wake of a resurgence of cattle tuberculosis.

d.) E. Coli Projects

In FY 1993, APHIS began two projects to analyze and disseminate information on E. coli O157:H7, the foodborne pathogen responsible for serious human illness and death in Western States. These projects included conducting a study on E. Coli, O157:H7 in ground beef and a follow-up study on the 1991-2 NAHMS Dairy Heifer Evaluation Project, which tested calves on 1,068 farms in 28 States to estimate E. Coli prevalence in U.S. dairy herds. Specifically, APHIS initiated a comprehensive assessment of E. Coli, O157:H7 in ground beef from farm to slaughterhouse. Also, the Agency analyzed preharvest animal management practices to gather information on the impact of management practices on food safety in general, and specifically E. Coli in ground beef. APHIS analyzed the results of the Dairy Heifer Project and conducted a case control study by re-testing the calves. This analysis demonstrated a very low prevalence of E. Coli, O157:H7 in U.S. dairy herds (less than one percent in calves and an estimated five percent of herds, as identified by fecal culture). APHIS also evaluated environmental and nutritional factors that influence the presence of E. Coli, and dairy calves' potential to act as long-term carriers, by comparing farms where the pathogen was identified to those where no infection was identified.

e.) Bluetongue

In FY 1993, APHIS conducted its annual bluetongue survey of cattle in 15 States. The results indicated that 13 of the States are bluetongue-free or have a low disease incidence with no major increase or decrease in infection. Indiana and North Dakota are the only two States with an incidence of bluetongue at or above the 2-percent allowance for less restrictive exportation of animals to Canada. The Canadian Department of Agriculture continues to use the survey results to allow livestock importation from low-incidence States with minimum testing requirements.

f.) Bovine Leukosis

In FY 1993, APHIS participated with industry representatives and members of the scientific community in developing the framework for a voluntary bovine leukosis-free herd certification program. Several States have certification programs for bovine leukosis, but this is the first attempt to develop a mechanism to recognize herds as leukosis-free on a national level. Bovine leukosis is a major obstacle to cattle exportation to the EC, where many member nations have mandatory control or eradication programs.

g.) Equine Diseases

Equine infectious anemia (EIA) is a viral disease of equine that causes fever, anemia, progressive weakness, and weight loss. The State-Federal cooperative EIA monitoring system revealed that in FY 1993, 1,859 (0.18 percent) of the 1,035,037 samples tested for EIA were identified as positive. In FY 1992, over 1,800 positive samples were identified out of approximately 857,000 samples, for an incidence of 0.22 percent. From FY 1992 to FY 1993, the incidence rate decreased by 18 percent. This decrease may be attributed to the interstate restrictions being placed on the diseased animals. Also, APHIS monitored the status of eastern and western encephalitis in the United States, and conducted surveillance for Venezuelan equine encephalitis. In addition, the Agency monitored the status of equine diseases internationally, with particular attention to African horse sickness. Also in FY 1993, APHIS continued to support cooperative research with Texas A&M University to develop more accurate and reliable diagnostic tests for equine piroplasmosis. In addition, APHIS assisted the thoroughbred industry in diagnosing and monitoring an outbreak of equine viral arteritis (EVA). EVA causes fever, conjunctivitis, edema, depression, and weakness. The first cases were identified at an Illinois racetrack, where over 160 horses were affected, but none died. The disease later occurred at several other racetracks in other States, but early diagnosis enabled officials to institute control measures, including vaccination and movement restriction.

h.) National Poultry Improvement Plan (NPIP)

NPIP, is a voluntary quality assurance program for the poultry breeding industry of the United States. Over 90 percent of all commercial egg-type breeding flocks in the United States that ship baby chicks or hatching eggs interstate participate in this program. The NPIP's mission is to prevent egg-transmitted and hatchery disseminated poultry diseases. In FY 1993, the "U.S. S. Enteritidis Monitored" program for egg-type chickens was amended to provide for screening meconium, cull chicks, and hatcher trays from egg-type chicken breeding flocks which had a positive environmental culture(s) but negative bird culture(s).

As a result of testing all participating poultry establishments, APHIS found a significant decline in SE prevalence in commercial egg-type multiplier breeding flocks compared to FY 1992, when there were 12 flocks with SE isolates. In FY 1993, no commercial poultry flocks, egg-type chickens, meat-type chickens, or turkeys, had S. Pullorum or S. gallinarum isolates. S. enteritidis (SE) was found in five commercial egg-type multiplier breeding flocks and these flocks lost their classification. Therefore, all products from these flocks were prohibited from being sold interstate. Hatching eggs from flocks with bird isolates were removed from the incubators and destroyed. Hatching eggs from flocks with bird isolates that had not been set in the incubators were diverted for pasteurization. The progeny from flocks with bird isolates were traced forward. In almost all cases, pullet growers chose to depopulate flocks with progeny from a breeding flock with a bird isolate, while others chose to have them environmentally sampled for SE.

In FY 1993, there were no isolates of M. gallisepticum (MG), M. synoviae (MS) found in primary egg-type and meat-type chicken and turkey breeding flocks. Also, there were no isolates of M. meleagridis (MM) in primary turkey breeding flocks. There was 1 egg-type multiplier breeding flock and 12 meat-type multiplier breeding flocks confirmed positive for MG. In addition, there were 6 egg-type multiplier breeding flocks and 20 meat-type multiplier breeding flocks confirmed positive for MS. Also, there were 10 turkey multiplier breeding flocks confirmed positive for MM. Arkansas became the 12th State to be classified as "Mycoplasma Gallisepticum Clean State, Turkeys" in FY 1993. Mycoplasmosis is a disease that causes annual losses of approximately \$150 million. In addition, New Mexico is completing the requirement for "Pullorum-Typhoid Clean State" status. This requires 2 years with no pullorum-typhoid isolated from any poultry in the State.

i.) Poultry Diseases

In FY 1993, APHIS tested over 300 poultry flocks in 12 eastern States for avian influenza (AI). In positive cases, the Agency established quarantines, carried out clean-up activities and provided technical assistance to poultry owners. Initial funding was provided from the line item before contingency funds were allocated in March 1993 to handle the emergency. In December 1992, a Pennsylvania turkey flock was identified as having been exposed to and infected by a potentially lethal type of AI. Trace-out from this premise implicated the live poultry markets (LPM) in Philadelphia, New Jersey, and New York City. The AI virus was isolated from 11 of 41 (27 percent) LPM's in New York, 5 of 28 (18 percent) LPM's, and 1 backyard flock in New Jersey and 1 of 2 (50 percent) LPM's and 1 backyard flock in Pennsylvania. These premises were cleaned, disinfected, and retested. The last premise, a New York LPM, became free of the virus in April 1993. Trace-outs were made to over 620 farms and premises in the north, east, and mid-atlantic areas. Poultry on 13 premises showed previous evidence of exposure to this virus subtype. This virus was non-pathogenic to poultry and the surveillance and control measures were precautionary. Other surveillance in Florida identified similar virus activity in three Miami Live poultry markets.

In the summer of 1993, two additional isolations of the AI virus were made from ratites, emus, and rheas in three Texas premises and one North Carolina site. Both types were potentially lethal to poultry and one was identical to that isolated from the New England market earlier in the year. The source of all infections was associated with two exotic

bird auctions in Texas, which were held in May 1993. All contact and sale birds were traced from these auctions. Over 120 trace-outs were made to 14 States, and evidence of the virus was found on 18 premises in 8 States. These premises were placed under quarantine until they tested free. Thirty-one States have now imposed health certification for the interstate movement of ratites.

j.) Swine Health Protection (SHP)

In FY 1993, APHIS continued to strengthen compliance and enforcement by continuously monitoring swine garbage feeding operations for presence of foreign animal disease. State and Federal inspectors conducted 42,888 inspections of approximately 5,134 licensed garbage feeding premises. This compares to 42,084 inspections of approximately 4,406 licensed garbage feeding premises in FY 1992. A total of 73,238 searches for unlicensed garbage feeders was conducted in FY 1993, as opposed to 77,355 in FY 1992. These inspections and searches resulted in 691 documented violations in FY 1993, compared to 638 in FY 1992. This increased number of violations identified is attributable to the improved quality of inspections. State and Federal inspectors have improved their methods of determining when feeding operations are cooking garbage so they can be present at that time to assure compliance with the Swine Health Protection Act. As of April 1992, violators became subject to "stipulation authority" and a \$500 fine if the violation occurs in a State where APHIS has primary enforcement responsibility (PER). This authority was instituted because the Agency considers it a better deterrent than the previous policy, which allowed for a \$5,000 fine but also led to significant time lapse while the case was appealed to an administrative law judge. Through "stipulation authority," APHIS is able to modify unauthorized activities more rapidly. Also in FY 1993, the Agency began conducting a risk assessment of the SHP program to determine the effectiveness of the program and to look for ways to improve efficiency without increased cost. This program is becoming increasingly important as an environmentally sound alternative to the use of landfills for used food waste.

Also in the area of swine health, all States are now finished or nearly finished with initial surveillance testing for pseudorabies to identify infected herds. All infected herds are being rapidly included in a plan to eradicate the infection. Slaughter surveillance is being used in 29 States to monitor for newly infected herds in those States. As this system is improved, more States will monitor sows and boars at slaughter. The system has the potential of being the most cost-effective method of locating a newly infected herd in a low incidence area.

k.) Tuberculosis (TB)

In FY 1993, APHIS continued to monitor the incidence of TB throughout the United States. In addition, the Agency tested 4,040 TB suspect tissue submissions in FY 1993. Of these, 448 (11 percent) tested positive for TB. Only 12 of the positive cases were adult cattle with the remaining 436 being immature feedlot animals. In FY 1993, the Agency completed tracebacks on 6 of the 12 adult cattle that tested positive with only 2 cases traced to an infected herd not previously known to be infected. Traceback was completed on 388 of the 436 immature feedlot animals. A total of 326 of the 388, or 84 percent of the feedlot cases were traced to Mexico, and 62 cases were traced to

their lot of origin at the feedlot. Generally, these cases are not traced back any further than the feedlot, because of the extreme difficulty in identifying the animal's source of origin at this point.

In FY 1992, 4,162 suspect tissue submissions were tested. Of these 613, or 15 percent, tested positive for TB. The number of suspect submissions decreased by only 3 percent from FY 1992 to FY 1993; however, the number of animals which actually tested positive for TB decreased significantly. APHIS believes that this significant decrease is the result of the Mexican State of Chihuahua putting a voluntary ban on the exportation of Holstein steers in FY 1991. In FY 1992, a number of pre-ban steers still remained in the feedlots. Because these steers were heavily infected with TB, the overall number of positive cases increased greatly. By FY 1993, the majority of pre-ban steers were no longer at the feedlots, thus bringing the total number of positive cases down.

2. Animal and Plant Health Regulatory Enforcement

Under this program, APHIS employs professional field investigators and staff specialists to ensure compliance with Agency regulations through a combination of sound enforcement and strong educational efforts. Activities include, but are not limited to, investigation of violations, documentation of evidence, and development of alleged violation cases for prosecution.

APHIS regulatory enforcement field personnel perform a number of enforcement activities including conducting field investigations, tracking unresolved violations cases, and coordinating investigative efforts within the Agency. When a violation is detected, APHIS policy is to first attempt to gain voluntary compliance through discussions with responsible officials, and take appropriate enforcement action only when this approach fails, i.e., violations are recurrent or flagrant. This could include a warning or stipulation issued by the Agency. However, when an investigation reveals apparent violations, a case report and documentation are forwarded to the Regulatory Enforcement staff who then determines the manner in which an alleged violation should be addressed for enforcement action. Those cases which warrant prosecution are then forwarded to the Department's Office of the General Counsel (OGC) for administrative or criminal action. At this point, OGC reviews the case to determine if there is a legally sufficient basis to warrant pursuit of further enforcement action and, if so, prosecutes the offending party on behalf of APHIS.

At the beginning of FY 1994, the program employed 72 field investigators stationed throughout the United States, who are assigned for administrative purposes to the program's regional sector offices in Annapolis, Maryland (Northeast); Tampa, Florida (Southeast); Ft. Worth, Texas (Central); and Sacramento, California (Western).

APHIS continued to work toward improving timeliness and accuracy in handling the increasing volume of violations. Between FY 1992 and FY 1993, the Agency experienced its most significant increase in the number of formal cases from 1,836 in FY 1992 to 2,697 in FY 1993. Since FY 1991 however, the average number of formal cases filed has risen 10 percent. Increased enforcement activity is also reflected in the number of civil penalties issued, which rose significantly from 1,428 in FY 1992 to 2,012 in FY 1993. In this regard, the Agency has made important progress in tracking cases through the implementation of a headquarters-

based online computer system. This system enables all investigators regardless of where stationed to enter data directly into the system with a laptop or personal computer.

APHIS regulatory enforcement personnel successfully conducted an extensive investigation of plant quarantine violations involving false phytosanitary certificates being used to move produce between Mexico, Texas, and California. This investigation involved close cooperation with the Government of Mexico to obtain original phytosanitary certificates to compare to the alleged false certificates.

Also during FY 1993, the program successfully completed a lengthy animal care investigation concerning fraudulent recordkeeping. This investigation resulted in prison sentences, home detention, and supervised probations for the violators.

In another case, RE personnel successfully conducted an extensive undercover investigation concerning fraudulent screening of livestock blood samples for brucellosis. This investigation resulted in a \$39,000 fine against a Mississippi livestock market operator.

3. Fruit Fly Detection

In FY 1993, APHIS continued to support and conduct cooperative fruit fly detection surveys in Alabama, Arizona, California, Florida, Georgia, Louisiana, Mississippi, New Mexico, South Carolina, and Texas, as well as Puerto Rico and the U.S. Virgin Islands. The purpose of these surveys is to detect new infestations of Medfly and other exotic fruit fly species.

During the past 5 years, outbreaks of various fruit flies have occurred almost annually in the State of California, especially in the Los Angeles basin. Currently, APHIS and the California Department of Agriculture are cooperating in a Medfly eradication project located in this region. Medfly outbreaks were eradicated from San Diego County in July 1993, and from Santa Clara County in October 1993.

APHIS and the State of California are also conducting a cooperative Oriental fruit fly eradication project in Los Angeles County in response to Oriental fruit flies having been captured in early September 1993. An Oriental fruit fly outbreak in San Diego County was declared eradicated in June 1993.

Other exotic fruit flies captured during FY 1993, as part of the detection program include: guava fruit fly, peach fruit fly, and the West Indian fruit fly.

4. Pest Detection

In FY 1993, APHIS and cooperators in the Cooperative Agricultural Pest Survey (CAPS) conducted surveys and managed the data collected. Data were managed in the National Agricultural Pest Information System (NAPIS) and in databases operated by CAPS cooperators. Data from these systems were used to provide Federal and State officials, and the private sector, with information on issues related to exotic pest detection, enhancement of agricultural exports, and management of cooperative pest control programs. APHIS provided approximately \$25,000 per State to the CAPS cooperators in support of this program. Cooperators included State Land Grant Universities or State Departments of Agriculture in 49 States and Puerto Rico.

A pilot project to evaluate capabilities for detection of an exotic bark beetle proved very successful. A small array of traps near a high risk site detected the spruce bark beetle. The high-risk material on the site was destroyed and a cooperative trapping program with the Forest Service and others was initiated. No further detections were made in an expanded, intense trapping array. It appears that a potential introduction of this serious pest was averted.

Detection and/or delimiting surveys were conducted for chrysanthemum white rust, apple ermine moth, cherry bark tortrix, Africanized honeybee, brown citrus aphid, pine shoot beetle, necrotic strain of potato virus-Y, Asiatic rice borer, cabbage moth, Caribbean fruit fly, Egyptian cotton leafworm, European cherry fruit fly, European grape berry moth, false codling moth, grape vine moth, large yellow underwing, light brown apple moth, maize borer, melon fly, peach fruit fly, pear leaf blister moth, plum fruit moth, Queensland fruit fly, rice cutworm/cotton leafworm, silver Y moth, Summer fruit tortrix, and other exotic species. Surveys were also conducted for biological control organisms and for their target species. Data were managed for these species as well as for gypsy moth, pink bollworm, imported fire ant, Medfly, grasshopper, and other cooperative program pests.

Operating features of the NAPIS database and the NAPIS data files continued to be improved. This led to improved performance and decreased cost of operation for the system. Annual direct cost of system operation was reduced more than 5 percent from the previous year. Operating speed increased 100 percent resulting in savings of time for the persons entering and retrieving data. The number of system users increased by approximately 10 percent.

Computerization of field data collection continued, resulting in improved ability to provide information more rapidly. The use of geographic information systems was initiated.

PEST AND DISEASE MANAGEMENT PROGRAMS

Current Activities: In cooperation with the States, APHIS works to improve the general health of our Nation's multi-billion dollar agriculture industry through management techniques designed to eradicate harmful pests and diseases, or, if eradication is not feasible, minimize their economic impact. Endemic diseases and pests are monitored through surveys to detect their location, and through inspections aimed at preventing their spread into noninfested parts of the country. Specific program efforts include:

Plant Pests and Diseases: APHIS Plant Protection and Quarantine (PPQ) Unit coordinates a number of programs which actively control or eradicate plant pests. Various tools are used, including pesticides, traps, and natural predators in order to control boll weevil, grasshoppers, gypsy moths, noxious weeds, and witchweed.

In order to prevent the spread of plant pests into noninfested areas, APHIS develops and enforces regulations concerning the movement and quarantine of plant materials. Extensive investigation and methods development are conducted to determine the most feasible and environmentally sound methods of dealing with golden nematode, imported fire ant, pink bollworm, and other miscellaneous pests for which there is no viable control method.

Animal Pests and Diseases: The Veterinary Services Unit of APHIS implements disease control and eradication programs involving testing, quarantine, treatment, and depopulation of infected animals. Brucellosis, cattle ticks, pseudorabies, and tuberculosis are program examples. The Animal Damage Control program protects American agriculture from detrimental predators through identification, demonstration, and application of the most appropriate methods of control.

Selected Examples of Recent Progress:

1. Animal Damage Control (ADC) Operations

Protecting American Agricultural Resources

The blackbird hazing and cattail management programs in North and South Dakota continued during FY 1993. Total requests for assistance were down from the previous year, primarily because of excessive rainfall. During FY 1993, ADC programs in North and South Dakota received 556 requests for aerial hazing activities. The goal of the hazing program is to scare blackbirds away from commercial sunflower fields, thus minimizing damage to the crop. During FY 1993, over 2,000 acres of cattails were treated with an EPA-approved herbicide. The cattail management program's goal is to reduce the amount of roosting and nesting habitat by controlling cattails in cattail-choked wetlands. By making the habitat unattractive, blackbirds are forced to seek suitable roosting and nesting sites away from sunflower fields. An additional benefit of controlling cattails is that by doing so, the habitat is improved for waterfowl.

ADC has continued its interagency agreement with the National Agricultural Statistics Service (NASS) to determine the magnitude and extent of wildlife damage to various agricultural crops. During FY 1993, NASS officials surveyed farmers in ten midwestern States to determine the extent of wildlife damage to field corn. Results from this survey will be available in early 1994.

In FY 1993, ADC program officials worked with representatives from Utah State University at Logan, Utah, to establish a new education program in wildlife damage management, and provided key funding for it. The program became a part of the Jack Berryman Institute for Wildlife Damage Management, which began operation in late 1992. The institute will become an integral part of the Utah State Department of Fisheries and Wildlife. Its main objectives are to provide educational opportunities to current and future wildlife damage management professionals, and to reward professional excellence.

A cooperative program between the North Carolina Resources Commission and ADC was implemented during FY 1993 in six North Carolina counties to reduce damage caused by expanding beaver populations. The program was initiated in response to numerous requests in those counties for assistance.

Protecting Human Health and Safety

ADC continued to provide assistance to John F. Kennedy International Airport in New York City. This is the third consecutive year APHIS has conducted operational gull control at the airport. As a result of the program, laughing gull bird strikes at the airport have been reduced by

68 percent, 92 percent, and 89 percent during FY's 1991, 1992, and 1993, respectively. Relocation of the laughing gull colony's nesting habitat has been identified as the optimal long-term solution to the problem.

APHIS continued to work with the Texas Department of Health to seek solutions to the problem of canine rabies which has spread to a 12-county area in south Texas. This particular strain of rabies originated in Mexico among feral dogs, and has spread during the past 3 years into south Texas, where both coyotes and feral dogs are now transmitting the disease. ADC is working with State and County officials to reduce coyote populations in and around densely populated areas where rabies has been found.

Protecting Natural Resources

The program continues to place emphasis on the protection of threatened and endangered species. During FY 1993, ADC personnel responded to requests to help protect the piping plover from gull predation in New York; the least tern and piping plover from mink predation in Nebraska; the Hawaiian stilt, moorhen, and coot from feral dog, cat, and pig predation in Hawaii; the desert tortoise from raven predation in California; and the snake river sockeye salmon from gull predation in Washington.

The Supplement to the Draft ADC Environmental Impact Statement (EIS) was released for public comment from January 22, 1993, through April 28, 1993. Approximately 95 comments were received and analyzed, prompting a determination by APHIS that additional work on the alternatives and economic analysis sections was necessary. The EIS is expected to be completed in early February 1994, with the Record of Decision to be signed 30 days later.

APHIS has been working with the government of Guam and the U.S. Department of the Interior to develop a cooperative program for control of the brown tree snake on the Island of Guam. The pest is widely established on Guam and has caused the virtual elimination of many avian species, including endangered species. Because there are no predators of this snake on Guam, it has continued to multiply rapidly. There is growing concern that the snake may disperse to Hawaii, and consequently to the continental United States, unless immediate control measures are taken.

A cooperative program for control of the brown tree snake on Guam began in April 1993, with establishment of a district office there. Program supervision is being provided by the Washington State office of ADC. In addition to APHIS, the Government of Guam and the Office of Territorial and International Affairs are helping to fund this effort. The program's goal is to establish snake-free zones around shipping facilities by trapping and removing snakes and making the habitat unattractive for the pest at shipping sites. The Department of Defense recently provided APHIS with an additional \$1 million for a cooperative brown tree snake control program at nine military locations in Guam and Hawaii. Work under the latter agreement began in August 1993, and will continue through the end of FY 1994. Direct control methods to be employed will include traps, glue boards, fencing, electrical barriers, detection dogs, and habitat modification.

2. Biological Control

Euonymus Scale

Euonymus plants are a versatile and attractive group of ornamentals that are grown in many parts of the United States. Many types of euonymus are susceptible to a small insect pest commonly known as euonymus scale. Without treatment, severe infestations of euonymus scale can kill all or part of the plant. In fact, because these scale attacks are so widespread and so difficult to treat, this ornamental is declining in popularity.

APHIS completed a second (final) year of baseline data surveys in 16 Northeastern and Southeastern States. These second year surveys were performed on a subset of the FY 1992 survey areas. First year surveys were conducted in 10 Central and Western States. Second (final) year surveys are projected for FY 1994 in these 2 regions.

Results indicate that the pest is most prevalent in States east of the Great Plains. Approximately 20 percent of the plants examined were heavily infested with scale. The predator, Chilocorus kuwanae has been found in most States along the Gulf and Atlantic coasts. A second year of data was taken to unequivocally confirm observations of the previous year.

APHIS is rearing two predator species and one parasite species from China acquired through cooperative efforts with the University of Massachusetts and Texas A&M University. APHIS and cooperators released these natural enemies into field insectaries and other protected locations in California, Indiana, Massachusetts, Michigan, New Jersey, and Tennessee. These sites will be used as future collection sites to provide natural enemies for redistribution. Although some releases were made in FY 1991 and 1992, FY 1993 was the first year that significant quantities of euonymus scale natural enemies were released.

Recovery surveys were finished at sites where surveys were not completed in FY 1992. The purpose of these recovery surveys was to determine the presence or absence of natural enemies released in previous years.

Baseline data surveys and establishment evaluation surveys yielded several new records in FY 1993. C. kuwanae was found in 13 out of 80 baseline data areas surveyed. Several finds reconfirmed records from FY 1992 surveys. New records include a New State Records in Oklahoma, and New County Records in Alabama and Tennessee. Cybocephalus were found in 4 of the survey areas. Establishment evaluation surveys yielded C. kuwanae at 3 out of 11 sites surveyed.

Cereal Leaf Beetle

Cooperators at the USDA, ARS, European Biological Control Laboratory supplied APHIS with limited numbers of the egg parasite Anaphes flavipes. These were increased at the National Biocontrol Laboratories in Niles, Michigan, and subsequently released at selected sites in Idaho, Montana, and Utah where this pest has recently invaded. Additional release stock was also obtained from locations in North and South Carolina. Field insectaries were established at four locations in North Carolina and Utah for receiving larval parasites in FY 1994. Survey samples indicate that the larval parasite Tetrastichus julis is established in parts of the Western United States range of cereal leaf beetle as well as in its Eastern range. This find in the West is

significant because T. julis was released in previous years, but not recovered. This natural enemy is one of the more significant agents proven to control the cereal leaf beetle in the midwest.

European Corn Borer

In FY 1993, APHIS rearing laboratories produced approximately 1.2 million Trichogramma ostrinae, an egg parasitoid introduced from China, to meet known cooperator requests for release material. The Trichogramma parasites were released by university cooperators in research programs to control the corn borer in New York and Massachusetts. This project will not be continued in FY 1994.

Russian Wheat Aphid (RWA)

The RWA is an invading pest of wheat, barley and other small grains currently found in 15 States and Canada. This pest has become a significant economic threat to agriculture affecting 53.6 million acres of wheat and 7.3 million acres of barley within those 15 states alone and presently has caused up to a 70 percent yield reduction in some areas. In FY 1993, APHIS reared and cooperatively released approximately 3 million exotic parasites and predators to promote biological control against the RWA. Releases were made in at least one site in each of the 9 Western States infested by this aphid. Special releases (i.e., releases that require intense manipulation and monitoring of the crop, pest, and beneficials) were also made with the assistance of USDA, Cooperative State Research Service scientists in California, Idaho, and Texas. Extensive surveys were conducted in fields that received release material during 1989-1991 (17 states) to determine the presence and impact of any exotic or native natural enemy species.

APHIS is proceeding to implement the recommendations made during a FY 1993 multiagency meeting on evaluation. Specifically, impact evaluation will be pursued in FY 1994 as a cooperative venture in 3 to 5 geographic areas over a 2 to 3 year period. APHIS and ARS jointly supported significant cooperative efforts on the taxonomic identification and impact assessment of released species as well as jointly conducting intense releases in Colorado.

Colorado Potato Beetle (CPB)

Mass production of biological control agents of CPB enabled release of approximately 670,000 agents for demonstration of the effectiveness of a biological control based potato crop management system. Approximately 130,000 Coleomegilla maculata, a coccinellid predator, and 130,000 Perillus bioculatus, a pentatomid predator, were released by cooperators during the first year of studies in Virginia. Approximately 114,000 Perillus bioculatus, and 296,000 C. maculata, were mass-produced by APHIS for release by cooperators in Delaware. Due to increased pesticide resistance and environmental contamination considerations, an evaluation of the economic and environmental benefits of this crop management system is in progress.

Sweetpotato Whitefly (SPW)

The SPW continues to cause significant losses to American agriculture. In 1992, the loss to cotton alone was approximately \$200 million. Until effective natural enemies are found, imported, and released for control application, an increasing amount of fruits and vegetables will be destroyed, creating shortages and higher prices nationwide. In FY 1993,

a year-long survey for the SPW and its natural enemies was conducted in the southern United States. Of the seven species of native parasites (five Encarsia and two Eretmocerus) discovered, all but one appeared to be widespread. Parasitization rates ranged from a low of 20 percent in spring to a high of 47 percent in winter in greenhouses and nurseries. SPW generally were less abundant where they occurred with native parasites, and a moderate level of density-dependence was noted. Species of exotic natural enemies now in production at Mission Biological Control Laboratory in Texas, include one coccinellid and seven aphelinids. DNA fingerprints have been obtained by rapid, polymerase chain reaction techniques. A total of 168,000 Encarsia formosa and 105,000 Eretmocerus mundus were produced for release in California and Texas. An additional 40,000 parasites were shipped to researchers in the United States and Mexico.

Leafy Spurge

Leafy spurge has taken over millions of acres of western grazing land. This aggressive, exotic perennial weed has greatly reduced the carrying capacity of the range. It readily out-competes desirable native vegetation. Because of irritating chemicals in the weed, cattle and horses generally do not graze on it, and they even avoid nutritious forage growing nearby. The damage costs ranchers an estimated \$35 to \$45 million per year. Several species of flea beetles, Aphthona spp., are now available for collection and redistribution from established populations in the United States and Canada for the control of leafy spurge. In FY 1993, APHIS collected 275,542 beetles within the United States for redistribution to new locations. In addition, 206,672 beetles were collected from Montana field insectary sites. Insects were released on leafy spurge at field insectary sites at 164 locations in 15 midwest and western States. These releases were in cooperation with State departments of agriculture and other State and Federal cooperators. Previous flea beetle release sites now show significant reduction of leafy spurge at these locations. APHIS designed studies to provide information regarding technology transfer and how to manage leafy spurge using alternatives to chemical control.

Diffuse and Spotted Knapweed

Ranchers constantly need to protect range plants that can support livestock against competition from unpalatable, inedible, and low-nutrient range weeds. Knapweeds are among these scourges. There are 25 knapweed species in North America. APHIS is involved in redistributing biological control agents throughout weed-infested states. At present, redistribution projects employ a number of insect species and are directed against spotted and diffuse knapweeds. These introduced weeds are serious pests of pastures and rangeland in the western United States and Canada.

In FY 1993, through cooperative efforts with scientists in Europe, APHIS successfully collected and cleared, through quarantine in Mission, Texas, nine species of biological control agents for knapweeds. These insects were shipped to and released at several field locations in various States. Additionally, collections of eight insect species from APHIS insectaries, now established in the United States, provided insects for redistribution to knapweed infested areas. The releases are for the establishment of field insectary sites on public lands for future redistribution of natural enemies within the respective States. Once these insectary sites are fully functional, individual State Department of Agriculture and County Weed Boards will make distribution to land managers and private owners. The benefit of this redistribution

effort is nationwide in that the environmental concerns are being met through stewardship activities of all personnel involved. A total of 76,232 insects were collected domestically, redistributed, and released at 69 locations in 12 States. The promising complexes of approved biological control agents for knapweeds include insects that feed on the foliage, eliminate seed production, and destroy roots.

3. Boll Weevil

Elimination of the boll weevil is a key component to effective cotton production in the future. Regions where boll weevil has been eradicated have realized a reduction in insecticide use ranging from 40 to 80 percent. This insect control/insecticide reduction translates to lower production costs, greater yields, and a cleaner environment. Estimates show that for every \$1 (Federal and State) spent in eradication, the industry accrues \$12 in benefits by eliminating the weevil from the treated area.

Studies indicate that the total annual direct economic benefits from increased yields, reduced insect damage, and lower insect control are \$81.6 million for the southeastern States participating in the eradication program. The annual losses for the States still not participating in the boll weevil eradication program are estimated to be \$546 million. This calculation is done assuming a conservative estimate of 10-percent crop loss in these States.

High Plains Boll Weevil Control Program

The boll weevil program treated about 1,357,000 acres in 1993, compared to about 453,000 acres treated in 1992. The increase in treated acres was due to unusually high weevil counts, caused by abnormally high overwintering populations. In FY 1993, the program succeeded protecting over 3 million acres of weevil-free cotton on the High Plains of West Texas and New Mexico. This was the second season in which the program used a satellite navigation and guidance system for aircraft treatment, significantly reducing the need for ground personnel.

Southeast Boll Weevil Eradication Program

The southeast eradication program continues to be successful. In FY 1993, Georgia, south Alabama, and Florida were involved in activities to confirm eradication. Northeast Alabama entered its first full season of program activity, while northwest Georgia and central Alabama joined the expanding program. Cotton growers in north Alabama and adjacent areas of central Tennessee and East Mississippi, voted to enter the program. The growers of all the expanding areas will pay 70 percent of the program costs.

The cooperative eradication program involved approximately 1,515,835 acres. Approximately 615,426 of those acres are in the post-eradication phase in Virginia, North Carolina, and South Carolina. The cumulative number of acres treated in 1993 was 1,528,101, which is significantly higher than the 390,945 acres treated in 1992. The increase was due to expansion into new areas in Alabama and Georgia and unusually high weevil populations in adjoining, non-program areas.

	<u>1991</u>	<u>1992</u>	<u>1993</u>
Total acres treated	224,442	390,945	1,528,101
Total weevils trapped	67,921	153,347	1,489,038

Southwest Boll Weevil Eradication Program

In FY 1993, post-eradication activities began in southern California and continued in most of Arizona. About 380,000 acres of cotton were planted in Arizona, about 2,400 acres in nearby Sonora, Mexico, and 1,600 acres in Caborca, Mexico. The acres treated fell, from 4,506 in 1992 to 3,928 in 1993. Ninety-eight percent of these treatments were applied in Caborca, Mexico. As weevils are eliminated in Caborca, the risk of reinfestation in Arizona and California decreases. In addition, APHIS maintained surveillance activities in Mexico to ensure that the boll weevil did not re-infest eradicated areas.

	<u>1991</u>	<u>1992</u>	<u>1993</u>
Total acres treated	420,171	472,000	384,000
Total weevils trapped	1,065	1,346	2,448

4. Brucellosis

Bovine

In FY 1993, APHIS protected the cattle and swine industries from brucellosis at an estimated cost of \$33 million. In the absence of a program, losses in the cattle industry alone could exceed \$900 million within 10 years.

As of September 30, 1993, 32 States, as well as Puerto Rico and the U.S. Virgin Islands, were designated Class Free. Seventeen States were in Class A status, and one state, Texas, was in Class B. During FY 1993, Oregon advanced to Class Free status.

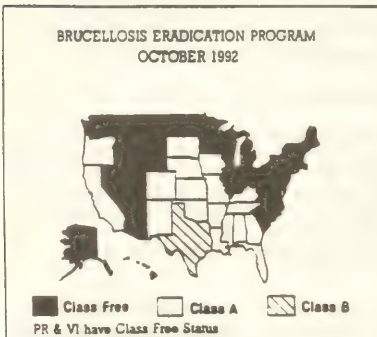


Exhibit 1 BRUCELLOSIS STATE CLASS STATUS AS OF OCTOBER 1992

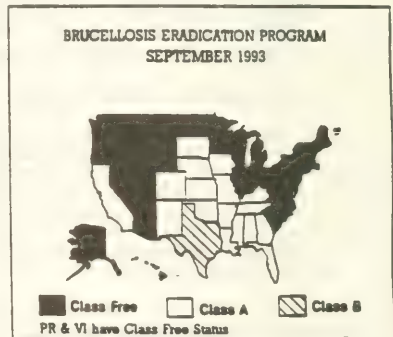


Exhibit 2 BRUCELLOSIS STATE CLASS STATUS AS OF SEPTEMBER 1993

The following table shows data for FY 1992 and FY 1993 in various brucellosis categories, the difference between the 2 years, and their percentage changes. Of the 14.4 million cattle tested for brucellosis in FY 1993, 2.5 million were sampled through herd tests on farms or ranches and 11.8 million were tested under the Market Cattle Identification program. Of the 601 reactor herds in FY 1993, 259 were located in States that were in Class A status at the end of the year and the remaining 342 were found in the one Class B State. As the number of

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infected animals and herds decreases, it is vital that the number of cattle tested increases, so that a strong monitoring and surveillance program is maintained.

Category	FY 1992	FY 1993	Diff.	% Change
Herds Under Quarantine for Brucellosis	415	283	-132	-32%
Number of Cattle Tested for Brucellosis	15,100,000	14,400,000	-700,000	-5%
Number of Reactors	13,300	16,746	+3,446	+26%
Number of Reactor Herds	744	601	-143	-19%

At the end of FY 1993, 9 dairy herds were under quarantine in the United States, with 6 of these in Texas. A task force made up of APHIS personnel, State employed veterinarians, and livestock inspectors in California's Chino Valley continued to make outstanding progress during the year, and have eliminated infection from the area's large dairies. California expects to apply for Class Free status in the near future.

A committee with representatives from the Interior Department, U.S. Forest Service, and the State of Montana is working on an Environmental Impact Statement on the brucellosis problem in the greater Yellowstone National Park area. APHIS continued to provide technical advice and options for eliminating brucellosis from the park.

In FY 1993, the Montana Game and Fish Department intercepted 72 bison as they were leaving Yellowstone National Park. Interceptions were made to prevent possible exposure of domestic livestock and other susceptible animals to brucellosis. Serological testing performed by Montana's diagnostic laboratory on the bison found 26 percent were negative, 63 percent were positive, and 11 percent were suspect. Tissues from 12 positive animals were collected at slaughter and 2 were culture positive for brucella abortus, the organism that causes brucellosis. A culture positive result means that the brucella abortus organism has been successfully isolated in a random sample of the infected animal.

The Agency continued to fund the vaccination of elk calves on 12 Wyoming feeding grounds. Funding was also provided for research at Texas A&M University on the transmission of brucellosis through embryo transfer.

Swine Brucellosis

The State-Federal-industry cooperative Swine Brucellosis (SB) eradication program is swiftly approaching its goal of complete eradication by December 1996. In FY 1993, Kansas and New Jersey became the 41st and 42nd States to achieve validated SB-free status. Eight States (Alabama, Arkansas, Georgia, Florida, Louisiana, Oklahoma, South Carolina, and Texas) remain non-validated with five States in Stage I and five States in Stage II. APHIS is encouraging these non-validated States to survey at least 10 percent of their breeding swine annually to detect SB.

SB prevalence is low, with only 51 infected herds, and the disease is primarily located in the Southeastern United States and Texas. Florida is the last major problem State with 25 infected herds as of June 1993.

Florida has nearly as many infected herds as the total number found in all other States combined. As of June 1993, 72 newly infected herds have been disclosed among all States, compared with 79 in June of 1992. Contributing to the disease's prevalence is the reluctance of owners to depopulate infected herds and the continual reinfection from feral swine in areas where swine brucellosis exists. Even though prevalence is low, there are still significant human health concerns. Workers at a North Carolina packing plant experienced a human brucellosis epidemic as a result of contact with infected hogs. Even after implementing all worker safety precautions established by the Occupational Safety and Health Act, there were still new cases. The only way to eliminate swine occupational hazard is to eliminate swine brucellosis from the domestic herds.

Also in FY 1993, APHIS coordinated conferences with State, Federal, and industry officials to discuss acceleration of the SB programs in States with feral swine. This involved representatives from Arkansas, Missouri, Oklahoma, Texas, Alabama, Florida, Georgia, Louisiana, Mississippi, South Carolina, and Tennessee. Industry participation consisted of swine producers and officials from the National Pork Producers Council, State producer organizations, and the American Farm Bureau Federation. After these conferences, the States submitted plans for accelerated SB eradication programs to APHIS. At the October 1993 United States Animal Health Association (USAHA) meeting, a resolution was passed encouraging innovative solutions for depopulating all infected herds by the end of FY 1994. APHIS is working with the swine industry to accomplish this goal.

5. Cattle Ticks

The cattle tick program is a cooperative Federal-State-industry effort to prevent the re-establishment of the cattle fever ticks, Boophilus annulatus and B. microplus in the United States; to maintain a permanent buffer zone along the Texas-Mexico border; and to eradicate the tropical bont tick, Amblyomma variegatum and the cattle fever tick, B. microplus, from Puerto Rico and the U.S. Virgin Islands.

In the continental United States, the program is concentrated along the Texas-Mexico border, where the Rio Grande serves as a natural barrier. During FY 1993, tick infestations were controlled through the use of a permanent quarantine zone, with systematic patrols, and inspections carried out by health inspectors on horseback. All livestock crossing the border and entering or leaving the quarantine zone were examined and treated for ticks to eliminate the risk of cattle ticks becoming established in the United States. As a result of this cooperative effort, cattle ticks have not become established beyond the original quarantine line which has been in place since 1936. By the end of FY 1993, there were ten infested premises under quarantine. Seven of these were in the tick eradication quarantine zone and three were in the free zone. All infested premises have been placed under quarantine and the livestock have been dipped, reinspected, and vacated from their infected pastures.

The tropical bont tick, A. variegatum, was first discovered in St. Croix, U.S. Virgin Islands in 1967 and in Puerto Rico in 1974 and was thought to be eradicated in FY 1991. However, tropical bont ticks were rediscovered in Puerto Rico in FY 1992 and in St. Croix in FY 1993. The premises involved in Puerto Rico remain under treatment with no new infestations. The affected premises in St. Croix were immediately

quarantined and livestock placed under treatment. Epidemiological investigations determined that the infestation on St. Croix was limited to one area north of Frederiksted.

In FY 1993, progress in the Puerto Rico cattle fever tick eradication program remained steady, with a 3-percent increase in the number of bovines in tick-free status. There has been little change in the total number of bovines pending treatment. At the end of FY 1993, about 6 percent of the total bovines were pending treatment.

6. Golden Nematode (GN)

In FY 1993, new infestations of GN were detected in 3 fields, for a total of 56 infested fields. All new detections are within regulated areas in New York. The State now regulates about 5,000 acres that had been infested with GN in the past, of which 206 are actively infested. The State implemented regulations to require the use of resistant varieties on land that has been or is currently infested with GN. In addition, potato growers in non-infested areas continue to increase the use of resistant varieties voluntarily. If GN becomes widely established in the United States, potential crop losses are estimated at no less than 10 percent of the \$2.2 billion potato industry.

7. Grasshopper and Mormon Cricket

In 1993, APHIS treated 85,000 acres compared to 236,000 in 1992. Each fiscal year APHIS conducts surveys in each of the Western States and a rangeland outlook map is developed and sent to cooperators for their information. In 1993, the survey was conducted and indicated that a possible 28,007,867 acres, which is approximately the same as the previous year, would be considered as heavily infested with grasshoppers and would require treatment. However, grasshopper populations in 1993 were very low due to the cool wet weather in the Western States. In FY 1994, APHIS plans to produce this map using Atlas Geographic Information Systems (GIS) computer base software. The Atlas GIS software improves the precision of the map by identifying the specific locations that may require treatment.

The following table shows acreage treated during FY 1993:

<u>State</u>	<u>Rangeland</u>	<u>Cropland</u>	<u>Total</u>
Colorado	638	0	638
Idaho	4,404	0	4,404
Montana	0	0	0
Nevada	2,117	0	2,117
North Dakota	59,298	864	60,162
Oregon	11,200	0	11,200
South Dakota	4,840	0	4,840
Utah	1,288	0	1,288
Wyoming	<u>6</u>	<u>0</u>	<u>6</u>
Total	83,791	864	84,655

APHIS continues to improve the HOPPER computer software program to be used by Federal and State land managers, and county agents when making decisions on grasshoppers control techniques. The HOPPER computer software identifies the technique that is most economically viable in each particular location based on weather conditions, type of

grasshopper, and economics. The software program was improved and the finalized version will be completed and made available to land managers in April 1994.

In FY 1993, the Grasshopper Integrated Pest Management program (GHIPM) developed new biocontrol options, such as Scelio spp and Entomophaga praxibuli. Both of the organisms are being reviewed by the APHIS Biological Assessment and Technical Support Staffs for environmental evaluation. In addition, the program developed an alternative chemical tool (Dimilin) as a candidate for registration. The program also developed a "Grasshopper Species Field Guide" and a "GHIPM User Handbook" containing a compilation of IPM technologies, for use in facilitating technology transfer. The program continued to make improvements in bait technology, active ingredient levels, and application rates. The program also initiated preventative "Hot Spot" treatments where localized outbreaks of 10,000 acres or less are treated before a devastating economic threshold is reached.

APHIS is working with a private company to obtain registration from EPA for an endemic plant pathogen Beauveria bassiana. This organism may be available within a year for controlling grasshoppers.

8. Gypsy Moth (GM)

Damage caused by GM varies with natural fluctuations in population levels and the rate of natural spread along the leading edge States. GM defoliation decreased from 2.4 million acres in FY 1992 to an estimated 2 million acres in FY 1993. As GM spreads, it will primarily attack hardwood trees with possible defoliations in excess of 50 percent resulting in weakened trees. Weakened trees experience a 30- to 50-percent reduction of radial growth which translates into at least 10-percent yield losses and increased production costs in the timber industry. In addition, trees that have been weakened by multiple defoliations are subject to heavy mortality. Although not preferred by the larvae, pines and hemlocks are subject to heavy defoliation during outbreaks and are more likely to be killed than hardwoods. A single, complete defoliation can kill 50 percent of pine trees and 90 percent of hemlocks in the infested areas. Losses will continue to increase as the generally infested areas expand along the leading edge.

The Agency's goal is to prevent the artificial, long distance movement of GM life stages to areas currently uninfested. APHIS accomplishes this goal by regulating the movement of logs, mobile homes, nursery stock, and outdoor household articles (OHA) from infested areas and eradicating isolated infestations when they do occur. In FY 1993, APHIS, in cooperation with State agricultural inspectors, conducted inspections and certified over 10,000 shipments of non-OHA regulated articles. Due to the large number of household moves out of the generally infested area (estimated to exceed 250,000 per year), self-inspection is allowed to supplement State and Federal resources for the regulatory control of OHA movement. Consequently, OHA movement represents the biggest risk for artificial spreading of GM. Up to 90 percent of all new isolated GM infestations are attributed to the movement of infested OHA's. APHIS also continued GM trapping and survey activities in the uninfested portions of the United States in an effort to detect isolated populations.

In FY 1991, the Asian Gypsy Moth (AGM), a very serious exotic pest, was detected in Washington and Oregon. FY 1993 was the second year of post-treatment survey to confirm eradication of AGM in Washington and

Oregon. Negative results of AGM testing from FY 1993 trappings will result in a declaration of eradication. However, in the summer of 1993, AGM was detected in survey traps in the Sunny Point, North Carolina port area. The AGM was re-introduced to the United States by a military vessel that came from Nordenham, Germany, on July 4, 1993. Trapping results indicated that the AGM had spread to areas as far as 30 miles from the Sunny Point terminal. APHIS, in cooperation with the Forest Service and the State of North Carolina, made an assessment of the extent of the AGM infestation to determine the feasibility and the financial needs of an eradication project.

9. Honey Bee Pests

In FY 1993, Texas had 68 counties under quarantine for Africanized honey bee (AHB). APHIS placed and serviced 400 traps to detect the spread of AHB in Texas. These traps are used to determine how far the AHB has migrated. The migration of the bees is closely monitored to assess the potential effect that the bees may have on agriculture. One trap line from Waco to Eastland along Highway 6 was taken over by Texas. All other APHIS traps were removed on September 30, 1993. The APHIS AHB identification laboratory in Harlingen, Texas, remained in operation during the year until it was closed permanently on September 30, 1993.

APHIS assisted the Arizona Department of Agriculture in establishing AHB trap lines along the Mexican Border and around Phoenix and other cities in Arizona. APHIS also loaned essential identification lenses to Arizona and New Mexico which were threatened by AHB invasions in FY 1993. Arizona intercepted AHB 23 times in FY 1993 in seven counties.

APHIS continues serving on the USDA Interagency Technical Working Group for Honey Bee, and in 1994 will chair this group. APHIS provided technical assistance to Texas, Arizona, and Alabama on AHB. APHIS has established an Assistant Operations Officer position in Phoenix, Arizona, that will assist the States with honey bee problems.

APHIS provides the National Agricultural Pest Information System to record all AHB survey information for availability to a wide range of users. By using information from this data base, APHIS readily provided infestation and expansion maps upon request. This data base is still in place.

10. Imported Fire Ant (IFA)

In FY 1993, APHIS assisted the State of Maryland in eradicating the IFA from a shopping mall in Frederick, Maryland. In addition, APHIS added 29 counties to the regulated area in the following States: Arkansas, Georgia, Mississippi, Oklahoma, South Carolina, and Tennessee. Survey work conducted in those States indicated that IFA had moved to those counties.

APHIS assisted with the registration of Tefluthrin by the Environmental Protection Agency to be used in the potting mixture for potted plants for shipment out of the regulated area. Tefluthrin is being reviewed by the APHIS Environmental Assessment staff for environmental concerns. In addition, APHIS revised the quarantine to include Bifenthrin in a three-tiered treatment to be used in the potting mixture for potted plants.

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APHIS revised the IFA quarantine map for distribution to the States, within the Agency, and the nursery industry. APHIS also revised "A Guide for Nursery Operators" for distribution to the nursery industry.

11. Miscellaneous Plant Pests and Diseases

In the international arena, APHIS facilitated surveys for several agricultural pests by offering technical advice to countries throughout the Caribbean, Central America, and Mexico. In FY 1993, APHIS conducted surveys for brown citrus aphid and citrus tristeza in the Caribbean.

Brown Citrus Aphid (BCA)/Citrus Tristeza Virus (CTV)

In FY 1992, an APHIS survey confirmed that BCA, the most efficient vector of CTV, occurs in Puerto Rico. In response to the discovery, APHIS in cooperation with other Commonwealth and Federal agencies conducted extensive surveys throughout Puerto Rico and the U.S. Virgin Islands. BCA was found to be well established in these locations. Other surveys indicated that BCA is established in the Dominican Republic and Haiti. Surveys were conducted in the Bahamas and Florida and the results were negative.

CTV causes three different disease conditions in citrus. The mild type, known as "Mexican lime vein clearing" type, is the one found in Puerto Rico. The moderate type, known as the "quick decline" type, is already present in parts of California and Florida. The third disease condition, known as the "severe stem pitting" type, is found in Bermuda.

The New Pest Advisory Committee recommended placing a high priority on development of biological control mechanisms for BCA. A pest alert for increased inspection of host material at ports of entry was issued.

In FY 1993, an International Workshop on BCA and CTV in the Americas was held in Venezuela to present research results and management strategies. In addition, APHIS coordinated a workshop to develop a list of actions and responsible parties should BCA/CTV be introduced into the U.S. mainland. APHIS is also developing an interagency technical work group to manage a BCA/CTV outbreak.

Japanese Beetle

There are two aspects to the Japanese beetle program. One is the regulation of hazardous airports (airports with high incidences of Japanese Beetle) to prevent the spread of Japanese beetles to noninfested areas. The other aspect is APHIS working with other Federal agencies and foreign countries to implement a regulation harmonization plan.

In FY 1993, the Agency treated airplanes at the Standiford Field Airport (Kentucky), Baltimore-Washington International Airport (Maryland), McGuire Air Force Base (New Jersey), Dover Air Force Base (Delaware), Toledo International Airport (Ohio), Philadelphia International Airport (Pennsylvania), Rickenbacker Air Force Base (Ohio), and Port Columbus International Airport (Ohio).

In FY 1993, APHIS presented a Japanese beetle harmonization plan to Canada for their review and approval. This plan will establish the harmonization of Japanese beetle regulatory activities between the

United States and Canada. The Agency is still negotiating the terms of the plan with Canada. In addition, APHIS implemented a domestic harmonization plan in FY 1993.

Pine Shoot Beetle

Pine shoot beetle (PSB) was first detected in a Christmas tree plantation on July 1, 1992, in Lorain County, Ohio. Subsequent surveys have detected the insect in 87 counties within 6 additional States: Ohio, New York, Pennsylvania, Indiana, Michigan, and Illinois. This beetle is reported to be the second most destructive shoot-feeding species in Europe. It is also the most destructive pest of pine.

Regulatory actions to control the interstate movement of regulated articles out of the quarantine area were imposed by APHIS and the States in November 1992. The infested States are supporting the cooperative program with interstate quarantine and cost sharing. The PSB program has nearly universal support from infested and non-infested States, other State and Federal agencies, and the regulated industries.

In FY 1993, APHIS conducted detection surveys at high-risk locations throughout the United States and extensive delimiting surveys around the known infested areas. Agency inspectors did not find any major PSB expansions into new States.

12. Noxious Weeds

This program prevents the entry of noxious weeds into the United States from foreign countries. Under the provisions of the Federal Noxious Weeds Act of 1974, APHIS works with State and local agencies to detect and prevent newly found or not yet widely established weeds from damaging U.S. agriculture. In FY 1993, program methods included port-of-entry inspections, weed identification, surveys to determine the scope of infestations, eradication feasibility studies, and other control and eradication projects. The program also conducted surveys and eradication feasibility studies on crupina in Idaho, goatsrue in Utah, itchgrass in Louisiana, and hydrilla in California and Florida. The Agency continued control efforts directed at common crupina, goatsrue, hydrilla, Salsola vermiculata, Orobanche ramosa, Orobanche Minor, and Cuscuta japonica. In addition, APHIS awarded a grant to the State of Florida to perform research and conduct control activities of Mimosa pigra.

13. Pink Bollworm (PBW)

In FY 1993, the PBW cooperative program continued to be successful in keeping this pest from invading cotton producing areas in the San Joaquin Valley, California. The number of non-sterile moths trapped in the San Joaquin Valley continues to decrease with 51 non-sterile moths trapped during the 1993 season, 115 moths trapped in 1992, and 263 in 1991. To achieve this, the program released 834 million sterile moths in 1993, an average of 6.1 million sterile moths released per day (based on 137 shipping days). The PBW program protects the \$1.3 billion cotton industry in California and Arizona, and prevents PBW from spreading to other non-infested States. Establishment of high populations of this pest in the San Joaquin Valley could cause yield losses and increase production costs of \$25 to \$50 million per year.

APHIS produced 834 million sterile moths at the moth rearing facility in Phoenix, Arizona. APHIS continued purchasing equipment for a new replacement rearing facility. The Agency spent \$1 million in FY 1993,

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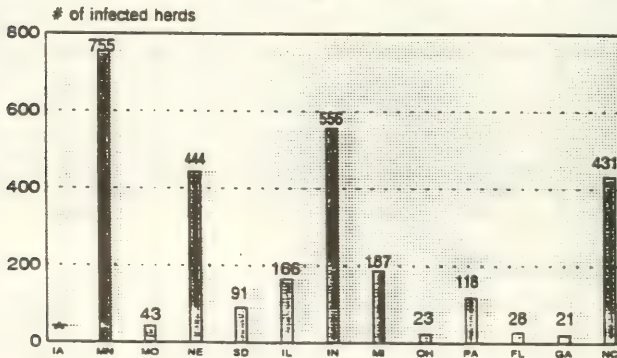
essentially completing acquisition of equipment for current level activities. Construction on the facility began on October 5, 1992, and production should begin in early spring.

Under the survey and quarantine enforcement part of the program, Mississippi and Arkansas remained on the list of quarantined States in FY 1993. In addition, because APHIS trapped PBW over the last three consecutive years in Missouri, the State was added to the list of quarantined States. Two Tennessee counties will be added to the quarantine list in FY 1994.

14. Pseudorabies Virus (PRV)

In FY 1993, 21 States in addition to Puerto Rico and the U.S. Virgin Islands progressed to the next stage in the PRV program and seven States (Alaska, Connecticut, Maine, Mississippi, New Mexico, Utah, and Wyoming) advanced to Stage V (Free) status. Eight States are in Stage IV. These States have no infections, but must remain in Stage IV for one year before applying for Stage V status. Twenty-one other States are in Stage III or have areas in Stage III. Stage III States/areas have only a low incidence of PRV. All States except Iowa have progressed in their eradication programs and the number of infected hogs in these States has been decreasing since June 1990. The United States now has its lowest level of infected herds since the PRV program began in 1988. The PRV-free swine herds play a crucial role in helping the U.S. swine industry become a major player in the international pork trade.

Pseudorabies States with Infected Herds

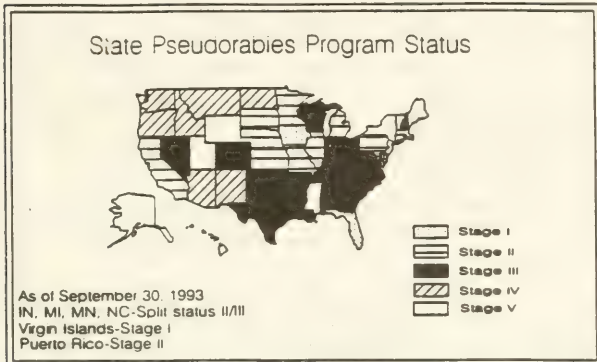


* Iowa reported 3,969 infected herds

** The following states have infected herds of 20 or less: KS, OK, TX, KY, MA, MD, NH, NJ, RI, VA, WI, AL, LA, SC, TN, CA, and CO

A 1987 Iowa State University cost/benefit study concluded that the U.S. swine industry, which has a production value of \$11 billion, directly and indirectly generates \$66 billion of economic output and 764,000 jobs each year, providing \$23 billion in personal income. This same study found that pseudorabies costs pork producers over \$30 million annually. APHIS continued to provide funding and technical support in FY 1993 for cost/benefit studies and economic evaluation to

assess the true costs of pseudorabies to the swine industry. In October 1993, Ohio State University's veterinary medical schools completed another cost/benefit study.



APHIS participated in various studies in Georgia, Florida, Texas, and California to determine what role, if any, feral swine play in PRV eradication from domestic swine. In addition, the Agency has been involved in risk analysis studies and negotiations to enhance international trade of live swine and/or pork products. Also in FY 1993, APHIS sponsored a national training program to provide essential information for all regulatory officials working with the PRV eradication program. The Agency also provided regional training programs that focused on specific State needs and resulted in enhanced program activities. New biotechnology advancements are continually being monitored and employed when appropriate to improve the program. In FY 1993, APHIS made improvements in new vaccines and diagnostic capabilities. The Agency continued to work with allied organizations such as practicing veterinarians, National and State Pork Producer organizations, American Farm Bureau, State Regulatory Officials, Swine slaughter and meat processing industries, universities cooperative extension service to discuss joint eradication projects. Also, the Agency assisted the Livestock Conservation Institute in sponsoring an annual meeting and distributing a monthly publication on the progress of PRV eradication.

15. Salmonella enteritidis (SE)

In FY 1993, the SE program continued to monitor human SE outbreaks and conduct tracebacks to flocks of origin for egg-associated outbreaks. A total of 57 human SE outbreaks were reported in Calendar Year (CY) 1993, compared to 54 in CY 1992. Eggs were implicated in 17 of the CY 1993 outbreaks, compared to 24 in CY 1992. Whenever eggs have been implicated in an outbreak, an area epidemiologist contacts the local public health service and collects invoices and packing information to determine the originating flock. In 12 of the 20 egg-related outbreaks, though, the outbreak could not be traced back to one particular source flock. Tracebacks are still in progress for two other outbreaks and tracebacks from one of the outbreaks led to an Indiana flock. One flock was depopulated before testing and another flock tested negative for SE.

To prevent SE outbreaks, APHIS continued an SE pilot project in Pennsylvania that began in April 1992. This project, which is a cooperative project between producers, the USDA, and the Pennsylvania Department of Agriculture, is designed to determine the best methods of preventing and controlling SE in egg-layer flocks. It now monitors approximately 5 million egg layers in 81 hen houses on 50 premises. The project's pertinent findings are being used to promote voluntary certification programs in areas where SE is a problem for egg-layer flocks. Its main objectives are to reduce the number of egg-associated SE cases and outbreaks and to study the epidemiology, transmission and risk factors involved in SE. Specific areas of interest include management and sanitation, cleaning and disinfection, rodent control, culture of the environment for SE, culture of eggs for SE, the role of chicks and pullets as SE risk factors, and the use of the SE vaccine.

This project has led to several major findings. Among these are that routine culture of eggs from an SE-affected flock can be used to determine SE risk for humans, that SE vaccine may reduce the number of SE-contaminated eggs in an SE positive flock, that SE in a flock does not appreciably affect the flock's mortality, morbidity, or egg production, that rodents play a prominent role in SE transmission among flocks, and that no flock in the project has been involved in a traceback from an SE outbreak since the start of the project. The project has also demonstrated that SE occurrence in eggs is extremely rare, although it has been shown to be present more frequently after molting. Specifically, the percentage of eggs contaminated with SE in affected flocks was .028 percent. As a direct result of this project, a Pennsylvania Egg Quality Assurance Program began in November 1993. This cooperative program is sponsored by the Pennsylvania Poultry Federation and supported by the Pennsylvania Department of Agriculture, Penn State University, the University of Pennsylvania, the Pennsylvania Animal Health Commission, producers, and the USDA. An estimated 200 flocks with 12 million birds are expected to be covered by this program, which uses control and testing procedures developed in the pilot project and should contribute significantly to preventing cases and outbreaks of SE caused by fresh shell eggs.

16. Scrapie

Scrapie continues to cause significant financial losses to sheep and goat producers across the country. Historically, it has resulted in annual losses of approximately \$2.5 million. In FY 1993, 120 flocks were diagnosed positive with one or more cases per flock. This is an increase of 53 from FY 1992. Of these 120 flocks, 10 had cases in previous years and 110 were new flocks with positive cases, compared to 56 in FY 1992. In FY 1992, 67 flocks were diagnosed positive, including 11 flocks with cases in previous years and 56 new flocks with positive cases. The increase in positive diagnoses from FY 1992 to FY 1993 can be at least partially attributable to the FY 1993 indemnity program.

On October 1, 1992, APHIS implemented the Voluntary Scrapie Flock Certification Program (VSFCP). This program was developed through the negotiated rulemaking process involving the sheep industry, allied industries, State animal health officials, APHIS, and other interested parties. The intent of the program is to monitor participating flocks for 5 years or more and to identify flocks free of scrapie. The program also contains provisions to restrict the interstate movement of animals from infected flocks and source flocks and to prevent the disease's introduction into scrapie-free flocks. Approximately 29 flocks enrolled in the VSFCP during FY 1993 and no infected sheep were

found in these flocks. Also in FY 1993, APHIS continued to support cooperative research between the Scrapie Investigation Center at Mission, Texas, and Utah State University to determine if embryo transfer provides a means of preventing scrapie transmission in sheep and goats. In addition, support was provided for cooperative research with the New York Institute for basic research, where scientists are working to develop a preclinical diagnostic test. Currently, no procedure is available to identify scrapie-infected animals before clinical signs appear.

17. Tuberculosis (TB)

As of September 30, 1993, 41 States and the U.S. Virgin Islands were in accredited-free status. Hawaii gained accredited-free status in FY 1993. Nine States including California, New York, Kansas, Louisiana, Pennsylvania, New Mexico, North Carolina, Oklahoma, and Texas are in modified accredited-free status. Puerto Rico is also in modified accredited-free status.

As of September 30, 1993, there were 12 confirmed infected herds quarantined for TB. Nine of these were carried over from previous fiscal years (eight infected and one exposed), and three were newly detected. The newly detected herds included one dairy herd in the El Paso milkshed area, which, as of September 30, had seven infected herds. The second detection was in a dairy herd in Texas and the third was in a herd of cattle and bison running in a commercial game park in Oklahoma with TB Cervidae.

Since January 1, 1991, TB has been confirmed in 24 captive cervid herds located in 13 States: Colorado, Montana, Idaho, Nebraska, New York, Indiana, North Carolina, South Carolina, Virginia, Missouri, Oklahoma, Texas, and Wisconsin. Ten of these herds were confirmed in FY 1991, 3 in FY 1992, and 11 in FY 1993. Of the 24 herds, 11 were depopulated by the owners without compensation, 9 remain under quarantine and are still being tested, and 4 have been tested and released. As a result of these confirmed cases, 68 additional herds have been exposed to TB.

In FY 1993, the Tuberculosis Committee of the U.S. Animal Health Association (USAHA) approved an APHIS-drafted tuberculosis addendum to the Bovine Tuberculosis Eradication Uniform Methods and Rules. The addendum provides for accredited cervid herds, official testing and follow-up procedures, and testing requirements for interstate movement. APHIS is currently making USAHA's recommended changes and finalizing the addendum for distribution.

Federal Meat Inspection personnel provided valuable support by submitting a total of 100 official Mexican eartags from tuberculous cattle found at regular slaughter. This allows APHIS to establish a steer's place of origin and other movement that may result from the sale of the cattle. Animal health officials in Mexico report that procedures have been implemented that will permit official eartags to identify the specific farm of origin. This will substantially increase the likelihood of successful tracebacks and provides new incentives for promoting official identification collection from all slaughter lots containing "M" branded cattle.

The project for supplying equipment to laboratories in Mexico for the diagnosis of tuberculosis continued with shipments made to the University of Mexico, Baja California, and to a laboratory in Mexico City. The equipment is acquired through the General Services Administration surplus property system at no cost to the Agency.

18. Witchweed

The program's goal is to prevent the spread of witchweed to host crop-producing areas of North Carolina and South Carolina, and move towards eventual eradication of this pest. In FY 1993, APHIS continued working closely with State and local governments, industry groups, and farmers to control witchweed. APHIS has eradicated witchweed from approximately 377,580 acres (87 percent of the originally infested areas). Twenty-four of 39 counties have been released from quarantine. In addition, APHIS continued progress towards ending direct involvement in the witchweed program. The current levels of infestation will allow APHIS to transfer the eradication program to the States by FY 1995. Afterwards, the Agency involvement will be limited to providing scientific and technological support to the States. In addition, APHIS will conduct post-eradication surveys and spot treat new infestations when detected. If allowed to spread into the corn belt, witchweed would cause an estimated 10 percent yield loss of the \$20 billion corn, sorghum, and sugarcane industries in the United States.

ANIMAL CARE

Current Activities: Under legislation first enacted in 1966 and amended several times thereafter, APHIS carries out activities designed to ensure the humane care and handling of animals used in research, exhibition, or the wholesale pet trade. Primary emphasis is placed on inspection of facilities, investigation of complaints, reinspection of problem facilities, and training of inspectors.

Regulations supporting the Animal Welfare Act (AWA), which appear in 9 CFR, Parts 1-3, provide minimum standards for the handling, housing, feeding, sanitation, ventilation, shelter from extreme weather and veterinary care of regulated animals. Birds, laboratory rats, and laboratory mice are currently excluded from these regulations, but legal action pending at the end of FY 1992 may cause their eventual inclusion.

APHIS performs prelicensing inspections because, according to statute, applicants must be in full compliance with AWA regulations and standards before a license is issued. After a license has been issued, program personnel perform unannounced compliance inspections and reinspections to verify continued compliance.

The program also conducts unannounced inspections of in-transit carriers and in-transit intermediate handlers to ensure humane care and handling of animals under their custody, and especially to ensure that adequate care is provided when a delay is involved. Registrants must refuse animals if the shipper does not meet regulatory standards. Inspectors carry out their inspections at major airports as resources allow, concentrating their efforts on times when animals are present.

If violations are discovered during a compliance inspection, APHIS establishes a deadline for correction, following which inspectors are required to make a reinspection. If the conditions remain uncorrected, APHIS documents them for possible legal action.

The Pet Protection Act was passed by Congress as part of the FACT Act of 1990. It sets specific holding periods for animals in public or private pounds or shelters and requires certification that the holding period has been met. The final regulations for this Act were published in the Federal Register on July 22, 1993.

APHIS is also responsible for administering the Horse Protection Act (HPA) of 1970 which prohibits the showing, sale, auction, exhibition, or transport of sore horses. Management of shows, sales, auctions, and exhibitions has statutory responsibility under the HPA to prevent unfair competition and must identify sore horses to prevent their exhibition, sale, or use.

APHIS inspectors monitor shows and sales for compliance and an industry self-regulation system known as the Designated Qualified Person (DQP) program which is the primary means of detecting sore horses. Horse Industry Organizations maintaining certified DQP programs participate with APHIS in yearly DQP training seminars and refresher clinics. Regulatory policy, procedures, and methods of inspection are reviewed throughout the year by APHIS in consultation with representatives of the horse industry to enforce and strengthen training programs. DQP's are evaluated for their compliance with all provisions of the HPA regulations.

Selected Examples of Recent Progress:

1. Animal Welfare

APHIS continued its efforts to increase the quality of inspections in FY 1993. The program implemented a comprehensive computerized inspection tracking system known as the Licensing Application Registration Information System (LARIS) to all sectors. This system increases program efficiency by providing an on-line database on AWA licensees and registrants as well as the capability for establishing a risk-based inspection ranking system.

APHIS inspectors conducted 2,213 prelicensing inspections, 2,368 carrier inspections, and 17,593 compliance inspections for a total of 22,174 inspections performed in FY 1993.

Through cooperation within APHIS to provide training and internship programs, APHIS continues its efforts to increase the quality of inspections. Two in-depth training courses on AWA regulations and standards were held at different locations in the field. However, due to a critical need to replace 22 high-mileage vehicles planned courses for inspectors in dealer recordkeeping and the other in water quality inspection for marine mammals were postponed until FY 1994. Other training efforts included continuation of the Exhibition Animal Internship program, as well as plans for implementation during FY 1994 of a Research Facility Animal Internship program.

In September 1993, APHIS held a 2-day public meeting in Oklahoma City, Oklahoma, to discuss issues of housing, care, handling, and unique practices concerning those farm animals subject to regulation under the AWA because of their use for nonagricultural purposes. The Agency will use the recommendations and proposed guidelines developed at this forum to further review and evaluate regulatory issues on this subject prior to formulating regulations covering farm animals used for nonagricultural purposes.

2. Horse Protection

During the FY 1993 horse show season, five HIO's monitored 495 shows, sales, auctions, and exhibitions. Of the 95,000 horses examined by DQP's at those shows, 1,140 were turned down because of noncompliance with the HPA (average turndown rate of 1.2 percent). Concurrently, APHIS personnel evaluated DQP's at 64 events. Approximately 2.04

percent of the horses were turned down in the presence of APHIS inspectors. APHIS personnel issued 25 Federal violations in FY 1993; in 20 of these cases, horses were documented as sore.

On January 29, 1993, regulations became effective amending the HP regulations applicable to DQP's in conducting inspections at shows, exhibitions, sales, and auctions. These actions are designed to add further safeguards against soring, and improve the methods of detecting sore horses. A similar proposed rule to amend the HP regulations regarding the presence of scars on horses foaled after October 1, 1990 is being developed in order to better protect horses under the Act. APHIS expects that these guidelines will improve the quality of inspections performed, while not placing an inordinate burden on the horse industry.

APHIS meets annually with representatives of the horse industry and associations such as the American Horse Protection Association (AHPA). Agency officials held an extensive meeting with industry representatives in January 1993, and participated in numerous discussions with various interest groups throughout the show season. APHIS personnel also met with industry owners, trainers, and committee members in a field setting.

Annual training of veterinary medical officers was conducted to acquaint new APHIS personnel with the HP program as well as to provide established VMO's with updates in policy and performance standards.

SCIENTIFIC AND TECHNICAL SERVICES

Current Activities: APHIS conducts programs to develop new or improved methods for reducing wildlife/agriculture conflicts, for controlling or eradicating harmful plant pests, and for applying new technology to assure the latest genetically engineered viral vaccines are pure, safe, potent, and effective. Additionally, the Agency conducts laboratory testing programs to support disease and pest control or eradication programs. Specific program efforts include:

Methods development: ADC methods development activities include: a program to develop blackbird damage-resistant sunflower strains; techniques for control of mountain beaver damage to western forests; methods to reduce rat damage to sugarcane and macadamia nuts, for reducing cormorant depredations of catfish, to improve single dose bait consumption by coyotes, to further develop and validate analytical methods of chemical analysis, to register and reregister chemicals compounds that are used for small mammal, bird, and predator control, and for taste aversion.

Biotechnology: Biotechnology has emerged as a force with the potential to improve existing products and spawn new technologies which could benefit agriculture as well as the general U.S. economy. Under its broad authority to protect plant and animal health, the Department has established a regulatory structure for bringing the benefits of genetic research from the laboratory to the marketplace, while protecting against the release of potentially harmful organisms into the environment.

Laboratory testing: The program for testing veterinary biological products is expanding to encompass testing for licensure of products destined for intrastate as well as interstate use, and the testing of genetically engineered products. The veterinary diagnostics program

continues testing in support of the Agency's animal disease prevention, detection, control, and eradication programs. In FY 1993, APHIS began collecting user fees for this program.

Selected Examples of Recent Progress:

1. ADC Methods Development

In FY 1993, the Denver Wildlife Research Center (DWRC) continued to develop and validate analytical methods of chemical analysis, and to register and reregister chemicals such as Compound 1080, strychnine alkaloid, zinc phosphide, Starlicide (DRC-1339), alpha-chloralose, and methyl anthranilate. These compounds are used for rodent, bird, and predator control, and for taste aversion. Approximately 55 percent of the methods development effort was devoted to developing alternative, nonlethal methods such as bird repellents, varietal resistance of crops to vertebrate damage, habitat manipulation, and immunocontraception.

In FY 1993, construction began on a new ADC methods development facility at Fort Collins, Colorado. This is the first phase of a three-phase project to relocate the DWRC from the current Denver site.

During FY 1993, ADC personnel in several Western States evaluated the potential of a new breakaway snare equipped with a shear-pin lock developed at DWRC. Additional field testing continued during FY 1993 to obtain observations encompassing a variety of field conditions. The improved locks were effective in allowing deer, antelope, and cattle to release themselves.

Among other projects, DWRC progressed in research to identify an immunocontraceptive for use on deer and other mammals as a method to resolve site-specific wildlife problems. Studies aimed at perfecting oral delivery of immunocontraceptives also continued. In addition, the program evaluated methyl-anthranilate as a bird repellent in aquatic situations with promising results. Birds can be repelled from water areas with new formulations that were tested. An electronic device for repelling beaver from problem areas, such as water control structures, was successfully tested.

During FY 1993, DWRC began a study to evaluate the efficacy of three sulfur-based repellents to protect seedlings from elk and deer browsing. This study is a part of an ongoing cooperative effort with the U.S. Forest Service to identify a method for alleviating wildlife damage on reforestation units. The program also began the first phase of the forward-looking infrared (FLIR) imaging study designed to determine the feasibility of using airborne FLIR technology to locate and conduct censuses of coyote and other wildlife populations.

ADC Methods Development personnel undertook studies of the brown tree snake problem in Guam under terms of an interagency agreement between DWRC and the U.S. Fish and Wildlife Service. DWRC research showed that methyl-bromide, as well as other fumigants and oral and dermal toxic insecticides, may be effective in controlling the pest. Fumigation of cargo that has a high risk of harboring snakes is one potential method for preventing their dispersal to other Pacific islands, including Hawaii.

DWRC submitted over 55 data volumes and labels, numerous amendments, and data waiver requests to the Environmental Protection Agency in support of vertebrate pesticide registrations. Each data volume supports a specific type of information that the Center is providing.

In addition, pesticide registration consortia consisting of APHIS personnel, private registrants, and State government officials, collaborated to provide data in support of product reregistration for strychnine, Starlicide, zinc phosphide, and methiocarb.

2. Biotechnology/Environmental Protection

Environmental Protection

In FY 1992, the Agency consolidated its three environmental units, Environmental Analysis and Documentation (EAD), Technical Support Services (TSS), and the National Monitoring and Residue Analysis Laboratory (NMRAL), under one division as part of an expanded *biotechnology/environmental protection* (BEP) line item. The action was taken to strengthen the Agency's ability to meet two key challenges of the 1990's: ensuring that APHIS functions as a good steward of the environment in its conduct of control and eradication programs both within and outside the United States, and serving as an effective and efficient regulatory bridge for the safe transfer of biotechnology products from laboratory to marketplace. Under the "circle of environmental protection" (CEP) concept, the BEP program helps the Agency comply with all environmental requirements--the National Environmental Policy Act (NEPA) and other statutes, regulations, and Executive Orders--in a proactive fashion.

The program's Environmental Analysis and Documentation (EAD) unit works with program planners to help identify and develop viable alternatives to current control and eradication programs, and documents APHIS' environmental planning activities. During FY 1993, EAD continued to work on an environmental impact statement (EIS) for Veterinary Services programs, and prepared a preliminary draft of the programmatic EIS for Medfly. On November 26, 1993, the Agency published a final record of decision for the Medfly EIS in the Federal Register. Altogether, the EAD unit prepared 27 environmental documents for APHIS programs during the fiscal year. These documents provided policy support and review for numerous environmental documents completed by program officials.

The second CEP component--Technical and Scientific Services--maintains registrations of chemicals and other substances used in current APHIS programs, while helping the Agency to identify emerging, less environmentally invasive alternatives to current practices. TSS also helps programs develop monitoring plans for assessing the impact of Agency actions on the environment. In FY 1993, TSS prepared monitoring plans for program activities and completed and distributed five environmental monitoring reports with detailed evaluations of residue data collected during control/eradication programs.

In order to meet the requirements of the Endangered Species Act (ESA), TSS designed guidelines to determine the effect of aerial spraying of malathion on established eagle nests, and designed a special eagle study for the gypsy moth program in Washington State. The Unit also collaborated with Penn State University and the University of Alabama in developing and implementing studies of aerial malathion drift, to satisfy Fish and Wildlife Service requirements, and the effects of malathion in streams on endangered species, respectively. TSS developed course material and provided training for Plant Protection and Quarantine field personnel regarding the NEPA requirements and other procedures involved in environmental monitoring. In addition, TSS provided assistance to APHIS' Plant Methods Development Center at Hoboken, New Jersey, in the development of a database for AQI program records.

The third link in the CEP, the National Monitoring and Residue Analysis Laboratory (NMRAL) at Gulfport, Mississippi, analyzes samples of soil, water, and crops for pesticide residue to ensure that the agency is conducting its programs in compliance with the Federal Insecticide, Fungicide, and Rodenticide Act; the Toxic Substance Control Act; the Toxic Substance Control Act; the Endangered Species Act; the Occupational Safety and Health Act, and other pertinent environmental statutes. The laboratory supports all APHIS programs--principally AQI, grasshopper, imported fire ant, boll weevil, Medfly, and gypsy moth--and performs reimbursable work for other USDA agencies and other entities for the analysis of pesticide residues and industrial chemicals. Work done for other agencies include analyzing pesticide residues in food commodities in Agricultural Marketing Service's Pesticide Data program which is intended to provide information to assure a safe food supply. During FY 1993, NMRAL conducted 9,796 chemical analyses for various pesticides including 3,985 analyses in support of APHIS programs and 5,811 analyses for other Federal agencies on a reimbursable basis. The laboratory also analyzed 75 plugs of trimedlure for potency and stability. The latter are used as part of the Medfly surveillance programs.

Biotechnology

Continuing the trend of recent prior years, APHIS experienced significant growth in workload, with an increasing volume of transgenic plants being tested in the field and coming to the market place. Since 1987, APHIS has experienced an increase in the number of release permits for field tests of transgenic plants, going from 5 field release in FY 1987 to 141 in FY 1993.

Based upon past experience and other relevant information, APHIS has concluded that the level of Federal oversight for such field tests and movement can now be reduced commensurate with the level of risk. To this end, the Agency moved in FY 1992 to amend the regulations to establish: (1) a notification process for the introduction of transgenic plants developed with genetic material from known plant pests, and (2) a petition process allowing determination that contains articles should not be regulated based on data developed from field trials.

Notification

Based upon our past experience of over 450 release permits and over 1,500 permits for movement of transgenic plants, we have established a notification process for both the field testing and movement of corn, soybeans, cotton, tomato, potato, and tobacco products. On March 31, 1993, the Agency published final regulations on the notification process. This process is based on the concept that it is possible for APHIS to assure that environmental risks will be minimal if a field test meets certain performance standards. The standards set the goal, but not the specific design protocols which researchers might use to achieve the performance standards. However, APHIS provides researchers with examples of possible protocols that are suitable for meeting the performance standards. If a proposed field test meets the prescribed standards, APHIS does not require a permit to conduct the test. The researcher simply notifies APHIS of the nature and location of the proposed field test, and certifies that the test will be conducted in accordance with the relevant standards. In turn, APHIS provides this information to the respective State regulatory officials. The Agency reviews proposed field tests that fail to qualify for the notification process under the current permitting process.

The new notification process allows a researcher to obtain authorization to field test or import one of the aforementioned crops within 30 days, or within 10 days for simple interstate movement. Following submission of a brief description of the regulated article, the site or destination, and a signed certification attesting to the responsible persons adherence to the notification eligibility criteria and performance standards, APHIS replies with an acknowledgement.

The notification process has proven to be more successful and better received by applicants than we had predicted. During the last 6 months of FY 1993, the Agency processed 117 release notifications and 79 movement notifications and 7 for importation. APHIS expects to issue over 500 notifications in the first full calendar year, and between 1,000 and 2,000 next year. This process is expected to save the Government approximately 10,000 to 20,000 staff-hours of work in the first year. Moreover, this new procedure has proven to be a cost-effective method of removing excessive regulatory burden on the biotechnology industry; an industry on the "cutting edge" in providing high tech employment. Equally important, APHIS has accomplished this increase in efficiency without compromising public safety, environmental safety or appropriate regulatory oversight.

Petition

On March 31, 1993, APHIS published regulations that established the petition process. These regulations allow for a determination that certain transgenic plants are no longer regulated articles, and define the information and data requirements for filing a petition for a determination of non-regulated status. APHIS is currently reviewing the petitions for the following three commodities: (1) virus resistant squash; (2) herbicide resistant soybeans; (3) and herbicide resistant cotton.

Together, these changes encourage innovative biotechnology research and rapid development without compromising safety. They also assure notification of States and the general public, and allow APHIS to focus its limited resources on petitions for release from regulation of more complex permit applications, and on efforts to harmonize biotechnology regulations between nations.

The Agency has been actively engaged in efforts to reduce barriers to international trade, and to foster the harmonization of regulations. In an effort to harmonize the regulatory oversight of genetically engineered plants and micro-organisms, APHIS personnel continued their active participation in United States/European Community bilateral environmental consultations and as members of the permanent Technical Working Group on Biotechnology and the Environment (TGBE). These efforts resulted in the issuance of the report of the second joint US/EC workshop on the release of transgenic plants which focused on case studies and approaches to risk assessment. The next TGBE meeting, to be held in FY 1994, will focus on the depth of data as well as how such data will be generated. This work has assumed heightened significance as a number of new plant varieties approach the final stages of variety development prior to commercial introduction.

In cooperation with the Organization for Economic Cooperation and Development (OECD), APHIS has been participating in an ad hoc technical group of government experts on Biotechnology for a Clean Environment. This group is developing a report that examines environmentally friendly uses of biotechnology, and highlights efforts of member nations leading to the development of biotechnology industries. In

addition, APHIS finalized and published a report focusing on the harmonization of approaches for safety assessment of biotechnology products entitled, "Report on the Seminar of Scientific Approaches for the Assessment of Research Trials with Genetically Modified Plants."

APHIS continues to work closely with individuals from numerous countries to share knowledge and experience in order to enhance the international harmonization of regulations. The government of Australia has sought the knowledge and expertise of APHIS in their efforts to develop a centralized national approach to regulating biotechnology products. Other specific activities have included working with officials from the Agency for International Development to host a regulatory capacity-building workshop for officials from Egypt, Kenya, and Indonesia, and hosting two separate week-long visits for individuals from the government and academic biotechnology communities of Thailand.

The program also continues to participate in efforts aimed at shaping the implementation of the Convention on Biodiversity to ensure that any provisions on biosafety that emerge do not unduly inhibit the development of our domestic biotechnology industry. APHIS is working closely with the Department of State to prepare a package of ratification documents for the Congress that explains U.S. Government policy and strategy in this regard.

Among other activities, APHIS continues to participate in the United Nations Conference on Environment and Development activities relating to national and regional biosafety capacity-building. The Agency helped to organize and participate in a Dutch government-sponsored meeting in Harare, Zimbabwe. In addition APHIS served, at the request of the United Nations Industrial Development Organization, on a panel on biotechnology regulation that visited the Russian Federation. The purpose of this meeting was to help the Russians in their efforts to develop a regulatory policy for biotechnology products consistent with sound scientific principles and with other regulatory approaches in other nations.

3. Integrated Systems Acquisition Project (ISAP)

The Agency released the ISAP Request for Proposals (RFP) on January 28, 1993. The release of the RFP was followed by extensive dialogue with interested vendors to clarify the Government's intent and requirements. Proposals were received on October 14, 1993. Contract award is expected during the last quarter of FY 1994. Additional program accomplishments include:

- The Source Evaluation and Implementation Board convened and started discussing the issues of an Agency-wide implementation of ISAP. This board is responsible for program-wide implementation planning including site specific requirements for hardware, software, telecommunications and support services. The board is also responsible for providing the Source Selection Board with an award recommendation based on technical and business findings obtained from analysis of the ISAP proposals.

- Established and trained the ISAP proposal validation and evaluation teams. An automated validation/evaluation system was developed to effectively track the review of the proposals and to identify ambiguities and deficiencies in the proposals.

--An Information Systems Planning (ISP) process has been instituted within APHIS. The ISP is identifying ways the Agency can improve management of information systems. By identifying the business needs of APHIS, the needs of the different functional units will be integrated into a shared data environment. The ISP effort will allow for the accessibility of information among all functional and organizational lines. This effort has been segmented into four basic levels with multiple tasks. The four basic levels are as follows: 1) definition of ISP, 2) architecture development or development of the data and process models for the business areas, 3) applications development, and 4) construction to include data element standardization and data dictionary development.

--APHIS initiated a Network Management System (NMS) analysis to position the Agency to effectively utilize and benefit from the ISAP solution. This step is necessary in order to operate the multiple, geographically distributed, shared databases in APHIS and a comprehensive Agency-wide electronic mail system.

4. Plant Methods Development Laboratories

The program is continuing to develop and improve advanced capabilities for detection, exclusion, containment, and management technologies for key exotic, introduced, and native pests, including insects, diseases, and weeds.

The Hoboken, New Jersey, Methods Development Center (MDC) continues to focus on new fumigation techniques, commodity treatments with heat or cold, and technical support to port inspection stations. Commodity treatment facilities are certified, risk assessments are accomplished, and stored product pest survey methods are perfected. Technical expertise is provided to update the APHIS treatment manual, develop fumigation standards, evaluate preclearance commodity treatment facilities, conduct aerosol and dust tests, and test plant products for tolerance to treatment. During FY 1993, final testing of a new fumigation enclosure was completed. This enclosure will ensure safer and more precise treatments in the field. In cooperation with ARS and Chile, a new non-chemical treatment for cherimoya (a tropical fruit), was developed. This treatment, which consists of soapy water and wax, has promise for use on other commodities to replace methyl bromide.

The Mission, Texas, MDC emphasizes pest-free areas provided by sterile insect release technology, chemical bait sprays, and other suppressive measures. Efforts are also directed toward improving quality control procedures for mass-produced fruit flies. Operational aspects of boll weevil eradication are being modified to eliminate low-density populations and reduce control costs. New bait formulations are also being tested. During FY 1993, methodology was developed to mass-rear a larval parasite of the MFF. Improved techniques to immobilize and field-deliver the parasite were also developed.

The Otis, Massachusetts, MDC has increased its emphasis on the development of new, and improvement of existing, European and Asian gypsy moth management techniques including biological control, mating disruption, sterile insect technique, pesticide evaluation, survey technology, and associated mass-rearing. Technical consultation is provided for eradication of isolated infestations throughout the United States. Regulatory treatments and management strategies are developed for the Japanese beetle, apple ermine moth, and pine shoot beetle. Biological control programs are focused on gypsy moth and RWA. During FY 1993, a new regulatory treatment for gypsy moth egg masses was

developed, as well as new pheromone dispensers for gypsy moth survey traps. The center has also developed the technology for molecular identification (DNA fingerprinting) of insects.

The Phoenix, Arizona, MDC is concentrating on development of a biologically-based system for pink bollworm management. Emphasis has been centered on development of an automated mass rearing system for production of sterile insects at lower cost. This has enabled an initiative to extend area-wide pink bollworm management into the Imperial Valley of California. An expert system is being completed to guide decisionmaking in the pink bollworm management program. New and existing grasshopper and Mormon cricket management techniques, including the development of microbial biocides, are being developed to reduce reliance on chemical pesticides. A commercially available strain of fungal pathogen is being tested for large-scale use against rangeland grasshoppers. During FY 1993, a methods development station was established in conjunction with ARS to conduct extensive evaluation of exotic parasites for the whitefly. Initiatives are also underway to explore fungal pathogens and an exotic predator in this cooperative program.

The Whiteville, North Carolina, MDC provides scientific and technical support to APHIS and its stakeholders for soil-related pests including witchweed, other noxious weeds, imported fire ant, and golden nematode. The center develops and assists in implementing biologically sound programs for the exclusion, detection, containment, and eradication of foreign weeds from the United States; provides new treatments for potting medium, to facilitate the movement of nursery products from areas infested with the imported fire ant; designs and tests new regulatory treatments for controlling imported fire ants in sod; and provides essential support to the witchweed program. During FY 1993, the Witchweed Operations Manual was edited to include changes in treatments available for witchweed eradication. After field testing, four new herbicides were added this year for project use. In addition, new application techniques were developed for metham sodium (Sectagon). Sectagon fumigation has been incorporated into the witchweed project at a cost of \$335 per acre as a replacement for methyl bromide fumigation which costs \$1,500 per acre.

5. Veterinary Biologics

APHIS conducts the veterinary biologics program under the authority of the Virus-Serum-Toxin Act of 1913, as amended. The Act provides USDA with the authority to regulate veterinary biologics imported to the United States, moved in intrastate or interstate commerce, or exported. The Agency issues a product license for production or a permit for importation after an applicant has met all requirements for product purity, safety, potency, and efficacy.

Consistent with recent trends, program activity continued to increase in volume and complexity in FY 1993. For example, APHIS issued 131 product licenses and terminated 67 product licenses for a total of 2,090 active licensed or permitted products in FY 1993 as compared to 2,026 in FY 1992. Producers presented APHIS with a total of 22,471 serials of veterinary biologics for release in FY 1993, of which APHIS withheld 1.55 percent for failing to meet Agency requirements. The NVSL tested 1,617 of the 22,471 serials.

APHIS investigators conducted 28 preliminary investigations related to possible violations of program regulations in FY 1993, resulting in the formal investigation of 13 cases. Forty-two regulatory actions were

taken in FY 1993. The program issued four warning notices, with no cases referred for criminal or civil penalties. The OGC is in the process of prosecuting two cases previously referred to them.

The program continues to develop new testing methods for veterinary biological products, while working at the same time to improve current tests. For example, NVSL is working on in-vitro potency tests for veterinary biologics, which reduce the use of laboratory test animals and are less costly and more accurate than laboratory animal testing. The program has established procedures for statistical analysis of data and maintenance of acceptable standards for in-vitro testing. This change should make it much easier for industry to use in-vitro testing in the future.

The veterinary biologics program has also moved forward with efforts to reduce trade barriers to the sale of products overseas. For example, program officials met with representatives from the European and U.S. biologics industries and regulatory officials from the European Economic Community (EEC). The intent was to start the process of harmonizing requirements for the production, testing, and licensing of veterinary biological products between the two trade partners. United States and EEC regulatory officials will continue efforts to work toward harmonization this year and to keep each other informed of regulatory requirements through exchange of proposed and final regulations and directives. APHIS will co-sponsor a seminar to be held in September 1994, on risk assessment procedures for the international movement of veterinary biologics, as a forum to identify and address questions of disease risk.

Harmonization with Canadian regulatory officials under the United States-Canada Free Trade Agreement has also helped bring about the harmonization of testing and inspection procedures. Future efforts will include the development of procedures to assure harmony is being maintained through mutual monitoring procedures. Veterinary biologics personnel have also given invited presentations in Mexico on licensing and inspection practices.

In August 1993, the Agency held a public meeting with licensed manufacturers to discuss proposed changes in test standards and procedures for Eripielas Bacterins. The following month, another public meeting was held address questions regarding proposed requirements for in-vitro testing.

To ensure responsiveness to consumer concerns, APHIS continues to maintain a toll-free hotline to address complaints about the potency, safety, and efficacy of veterinary biologics.

6. Veterinary Diagnostics

During FY 1993, the NVSL supported animal disease prevention, detection, control, and eradication programs; and provided diagnostic assistance to the livestock and poultry industries. There was continued emphasis on the isolation and identification of Salmonella enteritidis. Diagnostic support was provided for several programs that generated approximately 7,500 samples. In addition, over 35,000 cultures were submitted for Salmonella serotyping. Other activities included confirmatory testing of E. coli O157:H7 isolates and isolation of E. coli (K99) in support of the National Animal Health Monitoring System's Beef Cow/Calf Health and Productivity Audit.

In FY 1993, NVSL participated in rapidly establishing the cause of an equine viral arteritis (EVA) outbreak at a racetrack in Arlington, Illinois. The antibody against the virus was detected in 9 of 63 (46 percent) horses with clinical signs, and the virus was isolated from 24 of 37 (65 percent) infected animals.

NVSL also participated in the evaluation of the IDEXX gamma interferon test for the diagnosis of bovine tuberculosis. This involved the bacteriological and histopathological examination of multiple tissues from approximately 700 cows. The study is being done in cooperation with the National Animal Disease Center and the Texas Animal Health Commission and is expected to be finalized in early 1994.

NVSL processed and diagnosed more cases of bovine tuberculosis in FY 1993, than in any other year of NVSL's operation. Since FY 1986, the total number of bovine tuberculosis cases processed by the NVSL has increased three fold from 2,604 to 6,193 and the number of compatible cases have increased 10 fold from 70 to 697.

The Foreign Animal Disease Diagnostic Laboratory (FADDL) presented five Foreign Animal Disease Courses in FY 1993 - two for APHIS field personnel, one for university and state diagnostic laboratory personnel, one for Agriculture Canada regulatory personnel, and one for second year veterinary students.

A ribonucleic acid probe made from nonstructural protein-1 of African horse sickness (AHS) virus was used to successfully detect all nine serotypes of AHS virus in cell culture, using an *in situ* hybridization procedure. This probe was then applied to archive formalin-fixed tissue from 15 experimental cases of AHS, proving to be sensitive and specific. This procedure could be useful in diagnosing cases of AHS in the field.

During FY 1993, porcine reproductive and respiratory syndrome (PRRS) virus isolation attempts were successful on approximately 10 percent of over 3,000 samples tested. Serology for PRRS virus was done on nearly 40,000 sera. Approximately 27 percent of the samples were positive. The North American type PRRS isolate appears to be spread across the country, and serological studies indicate that a virus similar to European reference strains is established in certain areas of the country. Laboratory personnel have undertaken studies to determine the survival time of PRRS virus (both the North American and the European strains) in tissues from experimentally-infected pigs when stored at different temperatures. These studies have not been finalized but were started in response to a request by Russian scientists and trade officials. It appears that these studies may have trade implications far beyond the original intent including impacting shipping to and from Russia, Japan, and Mexico.

Monoclonal antibodies against peste des petits ruminants were tested for their ability to distinguish between the viruses of peste des petits ruminants and rinderpest in histologic sections. A monoclonal antibody was found which has excellent specificity and could be used to differentiate the two viruses in small ruminants during an outbreak.

During FY 1993, the NVSL assumed the histopathologic diagnostic responsibility for the Agency's BSE Surveillance Program and sampled 290 brain tissues from suspected BSE infected cattle. This responsibility was previously contracted out.

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CONTINGENCY FUNDSAvian Influenza

In January 1993, a Pennsylvania turkey flock was identified as having been exposed to and infected by avian influenza (AI). The trace-out from this flock implicated the live poultry markets in Philadelphia, New Jersey, and New York City. The AI virus was isolated from 11 of the 41 (27 percent) live poultry markets in New York, 5 of the 28 (18 percent) markets and 1 backyard flock in New Jersey, and 1 of 2 (50 percent) markets and 1 backyard flock in Pennsylvania.

The premises were cleaned, disinfected, and retested. The last location, a New York market, became free of the virus in April 1993. Trace-outs were made to over 620 farms and premises in the north, east, and mid-Atlantic areas. Poultry on 13 premises showed previous evidence of exposure to this virus subtype. This virus was non-pathogenic to poultry and the surveillance and control measures were precautionary. Surveillance in Florida identified similar virus activity in three live poultry markets in Miami. This past summer, two additional isolations of the AI virus were identified in ratites, emus, and rheas, in three premises in Texas and one in North Carolina.

Contingency funds were used to obtain \$780,000 of the estimated funds needed to detect, control, and eliminate the outbreaks, with the remaining \$185,000 coming from the poultry disease line-item.

Gypsy Moth

In FY 1993, APHIS conducted or-cooperated in gypsy moth control activities at 105 sites in 13 States. Treatments included both aerial and ground applications of Bacillus thuringiensis, Dimilin, and Gypcheck, as well as mass trapping operations. Infestations occurred as a result of the movement of outdoor household goods and uncertified nursery stock. APHIS and the U.S. Forest Service will continue to conduct control programs in isolated areas to prevent artificial movement of this pest.

Pine Shoot Beetle (PSB)

PSB was first detected in a Christmas tree plantation on July 1, 1992, in Lorain County, Ohio. Subsequent surveys have detected the insect in 92 counties within 6 States: Ohio, New York, Pennsylvania, Indiana, Michigan, and Illinois. This beetle is reported to be the most destructive pest of pine in Europe. Without the current program, the PSB could spread with conservative potential losses and increased production costs of no less than \$740 million in the entire U.S. to approximately \$3 billion in Georgia alone over the next 30 years.

In early FY 1993, regulatory actions to control the interstate movement of regulated articles out of the quarantine area were imposed by APHIS and the States. The infested States supported the cooperative program with interstate quarantines and cost sharing. In addition, APHIS conducted detection surveys at high risk locations throughout the United States and extensive delimiting surveys around the known infested areas. Results indicated that there were no major PSB expansions into new States.

Potato Virus Y (PVY-N)

PVY-N is a virus that attacks potato and tobacco crops, reducing their yields every year. If this disease becomes established in the United States, losses are estimated to be in excess of 10 percent of the \$5.2 billion potato and tobacco industries.

In FY 1993, APHIS met with representatives of the potato and tobacco industry, State departments of agriculture, Agriculture Canada, and the scientific community to discuss possible solutions to eradicate and avoid the spread of PVY-N. As a result, guidelines for a potato seed certification that should eliminate any threat of spreading PVY-N were developed. It was also determined that it is not cost-effective to perform additional survey and regulatory measures because eradication would not be guaranteed. Implementation of the seed certification system will allow for the removal of the current PVY-N regulatory system and permit resumption of normal trade of potatoes between the United States and Canada.

APHIS is waiting for comments on the proposal to remove those portions of the regulations that deal with PVY-N in Canada. When this process is completed, PVY-N will be regulated through the potato seed certification that the affected potato growing States are currently implementing.

Scrapie

In FY 1993, contingency funds were made available for scrapie indemnity. The indemnity program provided for the total depopulation of infected or source flocks or, at the discretion of APHIS and based on an epidemiological investigation, depopulation of high-risk animals in infected or source flocks. This program was limited to 6 months to encourage owners of eligible animals to promptly apply for indemnity and facilitate a rapid and thorough "clean-up" of flocks that may spread scrapie.

A total of \$1,016,300 in indemnity payments was made for 8,952 animals in 96 flocks. Total depopulation was carried out in 79 of these flocks and partial depopulation involving only high-risk animals was carried out in 11 of the flocks. In the remaining six flocks, a single animal was purchased for diagnostic purposes. APHIS had estimated receiving \$2 million in indemnity claims. This estimate was based on 200 known infected sheep and goat flocks of 60 animals each and the belief of the Negotiated Rulemaking Committee that 70 percent of these animals would be registered and 30 percent would be unregistered. Some ranchers may have been dissuaded to apply for indemnification because the indemnity plan lowered the amount of indemnity paid and because of new requirements in the revised regulations. These regulations required flock owners to participate in the flock certification program. Also, the plan had specific requirements for flock recordkeeping, new animal purchase, flock depopulations, actions upon animal deaths, and submission of diagnostic samples.

Screwworm

An outbreak of screwworm occurred in Mexico in FY 1992, with 61 positive cases having been detected in five Mexican States during the fiscal year. In response to this outbreak, the United States and Mexico initiated an emergency eradication effort involving intensive field surveillance and sterile fly dispersal in the affected areas and neighboring countries. On May 21, 1993, a positive sample was found in the State of Veracruz, Mexico, in an area just outside of the 1992

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eradication area. Four additional cases were detected in a small area near the junction of the two Gulf Coast Mexican States of Veracruz and Tamaulipas. The last positive sample in this outbreak was collected on June 17, 1993. Eradication activities for this outbreak ended in December 1993. In addition to \$825,000 in contingency funds provided in FY 1992, another \$1,575,000 was provided in FY 1993.

The United States/Mexico Commission production facility produced over 11 billion sterile insects during FY 1993, of which 3.6 billion were dedicated to the outbreak.

Tuberculosis (TB)

TB is a chronic, sometimes acute disease affecting cattle and dairy herds. On October 9, 1992, the Hillcrest Dairy Farm in El Paso, Texas, was tested for TB. Of the 663 animals tested, 269 were diagnosed positive for the disease. APHIS used \$649,000 of contingency funds to depopulate the herd. Through indemnity payments, the owner was able to more efficiently manage the termination and resumption of his dairy operation. The funds were also used to remove other reactor cattle that were disclosed throughout the year, and to remove and indemnify exposed cattle that had been sold to other herds.

In FY 1993 contingency funds were released for the following programs:

FY 1993 OBLIGATIONS (dollars in thousands)

	<u>Available</u>	<u>Obligated</u>	<u>Balance</u>
Avian influenza	\$ 780	\$ 555	\$ 225
Gypsy moth	729	664	65
Necrotic strain of Potato Virus Y	752	360	392
Pine shoot beetle	635	615	20
<u>Salmonella enteritidis</u>	166	127	39
Scrapie	1,920	890	1,030
Screwworm	1,575	1,575	0
Chrysanthemum White Rust	402	402	0
Tuberculosis	602	602	0
Unallocated			<u>315</u>
Carryover into FY 1994			<u>2,086</u>

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

The estimates include appropriation language for this item as follows (new language underscored; deleted matter is enclosed in brackets):

Buildings and Facilities

- 1 For plans, construction, repair, preventive maintenance, environmental support, improvement, extension, alteration, and purchase of fixed equipment or facilities, as authorized by 7 U.S.C. 2250, and acquisition of land as authorized by 7 U.S.C. 428a, [\$10,145,000] \$6,973,000, to remain available until expended (7 U.S.C. 2209b).

This change would provide authority for funding major preventive maintenance projects identified under the newly established APHIS Facilities Maintenance Program. The change would also provide APHIS with the authority to fund an environmental support program. It is anticipated that the need to be environmentally conscious will be a major factor on how the Agency develops its facilities. We now must adopt and comply with the Clean Water and Clean Air Acts, and safely and effectively monitor how we store hazardous waste and use underground storage tanks.

BUILDINGS AND FACILITIES

Appropriations Act, 1994.....	\$10,145,000
Budget Estimate, 1995.....	<u>6,973,000</u>
Decrease in Appropriation.....	<u>- 3,172,000</u>

SUMMARY OF INCREASES AND DECREASES
(on basis of appropriation)

<u>Item of Change</u>	<u>1994 Estimated</u>	<u>Program Changes</u>	<u>1995 Estimated</u>
Decrease of one-time construction projects in 1994.....	\$3,172,000	-\$3,172,000	--
Basic buildings and facilities repair, alterations, and preventive maintenance.....	<u>6,973,000</u>	<u>--</u>	<u>6,973,000</u>
Total Available.....	<u>10,145,000</u>	<u>-3,172,000</u>	<u>6,973,000</u>

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BUILDINGS AND FACILITIESPROJECT STATEMENT
(On basis of available funds)

	1993 Actual	1994 Estimated	Increase or Decrease	1995 Estimated
Total Obligations...	\$12,044,000	\$10,145,000	-\$3,172,000	\$6,973,000
Unobligated balance available, start of year.....	-40,216,000	-38,572,000	--	--
Unobligated balance available, end of year.....	38,572,000	18,282,000	--	--
Total Appropriated funds.....	\$10,400,000	\$10,145,000	-\$3,172,000 ⁽¹⁾	\$6,973,000

EXPLANATION OF PROGRAM

The APHIS appropriation "Buildings and Facilities" funds major non-recurring construction projects in support of specific program activities and recurring construction, alterations, preventive maintenance, and repairs of existing APHIS facilities.

JUSTIFICATION OF INCREASES AND DECREASES

- (1) A decrease of \$3,172,000 for buildings and facilities for one-time construction projects in FY 1994 (\$10,145,000 available in FY 1994).

Need for Change. Construction or design of the one-time projects identified in the FY 1994 request will be completed.

Nature of Change. The following projects will be built or designed with the funds requested in FY 1994 (in millions of dollars):

Construction of Phase IB of the Denver Wildlife Research facility in Ft. Collins, Colorado.....	\$2.000
Replacement of the Animal Predator facility in Millville, Utah.....	0.500
Expansion of the Plant Methods Development Rearing facility in Mission, Texas.....	0.672
	<u>\$3.172</u>

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

BUILDINGS AND FACILITIES

STATUS OF MAJOR CONSTRUCTION PROJECTS

Current Activities: The Buildings and Facilities appropriation funds major non-recurring construction projects in support of program activities and recurring construction, alterations, and repairs of existing facilities. The on-going major construction programs as of October 1993 are:

1. Plant Germplasm Quarantine Laboratory, Beltsville, Maryland - (\$3,800,000 available from the Fiscal Year (FY) 1990 appropriation).

The construction contract was awarded in April 1993. Construction began in April and completion is expected in April 1994. Through September 30, 1993, \$2,790,370 had been obligated.

2. Animal Research Building, Phase Ia, Fort Collins, Colorado - (\$6,000,000 available from the FY 1990 appropriation).

The construction contract was awarded in the fourth quarter of 1993. Construction began in August 1993, and completion is expected in December, 1994. Through September 30, 1993, \$6,000,000 had been obligated.

3. Outdoor Animal Holding Pens, Phase Ib, Fort Collins, Colorado - (\$2,500,000 available from the FY 1992 appropriation).

A design contract was awarded in October 1993. Design is anticipated to be completed in June, 1994. Through September 30, 1993, \$775,041 had been obligated.

4. National Plant Germplasm Quarantine Center: Phase I, Beltsville, Maryland - (\$12,000,000 available from the FY 1991 appropriation).

The Statement of Work for design is currently being developed by APHIS. Design will be completed in FY 1994. Construction is expected to begin in the second quarter of FY 1995 with completion in the second quarter of FY 1996. Through September 30, 1993, no funds had been obligated.

5. National Germplasm Quarantine Center: Phase II, Beltsville, Maryland - (\$12,000,000 available from the FY 1992 appropriation).

The Statement of Work for design is currently being developed by APHIS. Design is anticipated to be completed by the first quarter of FY 1995. Construction is estimated to begin by the third quarter of FY 1995. Through September 30, 1993, no funds had been obligated.

6. Plum Island Animal Disease Center Consolidation, New York - (\$5,000,000 available from the FY 1991 appropriation and \$1,737,450 available from the FY 1992 appropriation).

This was a joint construction project between the Agricultural Research Service (ARS) and APHIS. ARS awarded the contract for construction during FY 1993. All funds were obligated in FY 1992.

PASSENGER MOTOR VEHICLES

The 1995 Budget Estimates propose the purchase of 170 replacement passenger motor vehicles, approximately 25 percent of the Agency fleet.

The passenger motor vehicles of the Service are used by veterinarians, animal health technicians, plant protection and quarantine officers, inspectors, wildlife biologists, and other technical personnel in the performance of their duties. APHIS personnel use passenger motor vehicles during their daily activities to travel between individual ranches, farms, orchards, nurseries, ports, and other commercial firms. Use of common carriers is not feasible because of the need to travel in mostly rural areas. Comparative cost studies have shown that it is more economical to use Government-owned vehicles rather than reimburse employees for the use of privately-owned vehicles.

The Service's policy is to pool vehicles for use as much as possible. This results in a minimum of passenger motor vehicles and reduces overall operating costs. Personnel are required to maintain and submit operational data. These periodic surveys are made to determine the continued need for vehicles and their condition.

Replacement of passenger motor vehicles. APHIS proposes replacing 170 of the 679 passenger motor vehicles in the Agency fleet. Of the 679 vehicles, 565 vehicles are estimated to be in operation at the beginning of FY 1994, 87 vehicles have been sold and not yet replaced, and 27 vehicles have been ordered and not yet delivered. These 565 vehicles are located in field locations and are used for pest and disease exclusion, plant and animal health monitoring, pest and disease management, animal care, and scientific and technical services programs. The control, eradication, testing, and inspection activities are essential in protecting the Nation's multi-billion dollar agriculture industry. All vehicles proposed for replacement have 60,000 or more miles or are more than 6 years of age.

Age and mileage data for passenger motor vehicles on hand as of September 30, 1993, are as follows:

Age Data			Mileage Data		
Age-Year Model	Number of Vehicles	Percent of Total	Lifetime Mileage (thousands)	Number of Vehicles	Percent of Total
1988 & older	171	30%	80 or more	124	22%
1989	32	6%	60 - 80	95	17%
1990	153	27%	40 - 60	111	20%
1991	111	20%	20 - 40	137	24%
1992	66	11%	20 or less	98	17%
1993	32	6%			
TOTAL	565	100%	TOTAL	565	100%

AIRCRAFT

There are presently 23 aircraft in the Agency fleet, 9 for domestic plant pest and disease programs, 12 for animal damage control programs and 2 for international plant and animal pest exclusion programs. During FY 1993, APHIS acquired three surplus aircraft from the Border Patrol of Immigration and Naturalization Service at no cost. APHIS aircraft make aerial surveys and aerial application tests, are used for insect trapping operations, and are used to demonstrate special equipment for suppression of destructive insects attacking crops.

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Replacement aircraft, if purchased, would be used primarily in pest and disease management programs. These aircraft are sometimes used to supervise and observe contract planes which are newer, faster models than those the Agency has available. While this replacement authority is requested each year in the appropriation act, the aircraft are replaced only when necessary to maintain the fleet in safe and efficient operating condition.

Mr. DURBIN. The following are questions and responses that were submitted for the record on the budget request for the Office of Communications and the Agricultural Research Service—Human Nutrition Information Service activities.

OFFICE OF COMMUNICATIONS

CONSOLIDATION

Mr. DURBIN. When the Secretary took office last year, one of the first initiatives he announced was his plan to consolidate all public relations personnel from each agency into a single office at Headquarters. When Ms. Webb appeared before the Subcommittee last year, she had only been on the job about five weeks. At that time, she was about to begin an evaluation of how to reorganize the public affairs activities within the Department, looking at duplication of services across agencies and duplication of personnel. A Working Group, composed of career public affairs people from several agencies, was established. This group was to develop recommendations for the Secretary. What were the recommendations of this Working Group?

Response. The recommendations of the working group made in June of last year were:

Communication Coordinators—Establish communication coordinators at the Under/Assistant Secretaries levels. These people provide information support and coordination functions, vertically and horizontally, with all other USDA information support levels. Implementation of this recommendation is completed.

Farmers Information Survey—Commission an opinion survey of the American farming sector to determine where they get their information about USDA programs and other kinds of information important to their work. Implementation of this recommendation is completed.

Comprehensive Communications Audit—Request agency administrators to conduct a comprehensive communications audit of information, staff skills and all print, video, public service announcements, exhibits and related information materials currently in use, in production, or planned. The Department and agencies would then use this audit as a baseline for eliminating unproductive communication expenditures and improving the effectiveness of communication products planned for the future. The audit would also provide baseline data for a USDA-wide inventory of available publications and other communication products for response to public requests. Implementation of this recommendation is in progress.

Printing Reduction—Following the audit, call on agencies to achieve a reduction in their printing budgets for each of the next three years. Implementation of this recommendation is in progress.

Encourage agencies to use creativity in providing information to customers, while reducing printing costs, such as making better use of electronic formats, cost sharing with other agencies and organizations, using less expensive printing materials, producing fewer but better targeted publications, having more direct contact with customers instead of substituting printing pieces. Implementation of this recommendation is in progress.

Review of Regulations—Establish task teams of agency and Department specialists to review and update appropriate sections of Departmental regulations. Include a general Department and agency review process before implementing. Implementation of this recommendation is in progress.

Electronic Media Feedback System—Streamline all agency newspaper clipping functions and move toward one coordinated electronic feedback system that can be used by all. Expand the AG a.m. function to encompass agency interests as well as the Secretary's. This provides one-stop shopping for the Department and a broad overview of media coverage of USDA programs. A mechanism must be built into the system by which agencies may flag specific topics or hot issues to be targeted during sensitive periods. Agency and Departmental newspaper/popular periodicals subscriptions should be drastically reduced or eliminated. Implementation of this recommendation is completed.

USDA Customer Service Center with 1-800 number—Establish a USDA Customer Service Center with a nationwide 1-800 USDA number. When the call is received, it will be handled by USDA personnel or electronically if not staffed 24 hours a day. One of the new touch tone, interactive, menu systems would work well on non-staff hours. Implementation of this recommendation is in progress.

Regional Information Coordination—Create a communication structure that provides for the coordinated flow of clear and consistent messages from the Secretary

of Agriculture all the way to general and targeted audiences at the regional and State levels. Implementation of this recommendation is in progress.

ESTABLISHMENT OF THE OFFICE OF COMMUNICATIONS

Mr. DURBIN. On September 5, 1993, the Secretary abolished the Office of Public Affairs and established the Office of Communications. Tell the Committee how this new office is different from the old one?

Response. The new Office of Communications—OC—is structured into fewer program units, all reporting directly to the Director of Communications. The layer of mid-level management was eliminated in the restructuring. The new organizational structure reflects the Administration's call to increase the average span of a manager's control.

COST EFFICIENCY OF THE NEW OFFICE OF COMMUNICATIONS

Mr. DURBIN. One of the goals stressed by the Secretary is that USDA become more cost efficient. How has the creation of a new office made the Department more efficient? What savings, in both dollars and staff, have resulted from this change?

Response. The creation of the new office has made the Department more efficient in that it has a less structured and more flexible team, approach to how we get the work done. For example, the creation of two new teams—the News, Information Planning and Placement Team, and the Production and Creative Service Center—represent a multi-medium approach to both the creation and oversight of news and information production.

OC is eliminating duplication of services, which will ultimately result in a cost savings. It is too early to determine the savings, in both dollars and staff that will result from these changes. However, a more effective, efficiently run organization results in a better allocation of resources.

PUBLIC AFFAIRS ACTIVITIES WITHIN USDA

Mr. DURBIN. Tell us how many agencies at the Department have their own public affairs personnel? Why is there a need to maintain separate public affairs offices at the agency level?

Response. Twenty-three USDA agencies have their own public affairs/information personnel. Four economics and statistics agencies and offices share a combined public information staff. It has been necessary to maintain public affairs/information personnel in separate offices close to agency program officials so that public and news media requests for information can be responded to quickly and accurately. Two rural and small community development agencies share one public affairs staff. As part of USDA's overall reorganization, we've recommended 10 public affairs staffs across the Department.

Mr. DURBIN. How are your functions and responsibilities coordinated with these individual agency offices?

Response. The functions and responsibilities are coordinated with these individual agency offices primarily through our new staff of communications coordinators, each of whom is responsible for coordinating public information programs within specific mission areas of the Department. Each coordinator works closely with the respective Under or Assistant Secretary responsible for the program mission area. In addition, other units within OC provide creative information services and assistance to agency public affairs/information staff as needed. Finally, twice a month the Public Affairs Council—PAC—meets to share ideas, resources and the coordination of projects.

Mr. DURBIN. Provide a table for the record showing, by agency, the staff levels and dollars devoted to public affairs activities for fiscal years 1992 through 1994. [The information follows:]

USDA PUBLIC AFFAIRS ACTIVITIES
(Dollars in Thousands)

AGENCY	1992		1993		1994	
	Employment	Staff Years	Employment	Staff Years	Employment	Staff Years
Off. of Communications:						
Professional	89	89	93	87	92	92
Clerical	22	19	22	18	25	25
Budget Auth.	\$8,570		\$8,682		\$8,570	
ARS:						
Professional	44	46	44	43.8	44	43.8
Clerical	7	7	8	8	8	8
Budget Auth.	\$3,355		\$2,823		\$2,884	
CSRS:						
Professional	1	1	2	1.7	2	2
Clerical	1	1	1	0.9	1	1
Budget Auth.	\$66		\$108		\$137	
Extension Ser.						
Professional	7	7	7	7	7	7
Clerical	2	2	2	2	2	2
Budget Auth.	\$446		\$455		\$465	
NAL:						
Professional	2	2	2	2	2	2
Clerical	1	1	1	1	1	1
Budget Auth.	\$183		\$169		\$176	
FAS:						
Professional	16	16	15	15	14	14
Clerical	2	2	2	2	2	2
Budget Auth.	\$1,026		\$1,020		\$1,040	
OICD:						
Professional	1	1	1	1	1	1
Clerical	0	0	0	0.3	0	0
Budget Auth.	\$57		\$65		\$60	
ASCS:						
Professional	15	15	14	14	14	14
Clerical	6	6	6	6	6	6
Budget Auth.	\$1,270		\$1,312		\$1,402	
FCIC:						
Professional	3	1.5	2	1	6	4
Clerical	1	0.5	1	0.5	1	0.5
Budget Auth.	\$85		\$70		\$198	
REA:						
Professional	3	2.5	3	2.2	3	2.4
Clerical	1	0.5	1	0.5	1	0.3
Budget Auth.	\$137		\$120		\$138	
FmHA/RDA: 1/						
Professional	4	4	4	4	8	7
Clerical	1	0.5	1	0.5	5	4.7
Budget Auth.	\$270		\$280		\$710	
SCS:						
Professional	125	125	125	125	120	120
Clerical	26	26	26	26	25	25
Budget Auth.	\$7,300		\$7,400		\$7,400	
APHIS:						
Professional	19	19	18	18	17	17
Clerical	1	1	2	2	2	2
Budget Auth.	\$1,118		\$1,166		\$1,125	

USDA PUBLIC AFFAIRS ACTIVITIES
(Dollars in Thousands)

AGENCY	1992		1993		1994	
	Employment	Staff Years	Employment	Staff Years	Employment	Staff Years
FGIS:						
Professional	1	0.8	1	0.8	1.0	0.8
Clerical	0	0	0	0	0	0
Budget Auth.	\$39		\$42		\$50	
AMS:						
Professional	5	5	5	5	5	5
Clerical	1	1	1	1	1	1
Budget Auth.	\$322		\$342		\$406	
FSIS:						
Professional	47	42.2	55	46.6	56	47
Clerical	9	8.5	9	8.6	9	8.6
Budget Auth.	\$2,800		\$3,300		\$3,300	
PSA:						
Professional	2	1.6	2	1.6	2	1.6
Clerical	0	0	0	0	0	0
Budget Auth.	\$55		\$62		\$65	
ACS: 1/						
Professional	4	4	4	4	(4)	(4)
Clerical	4	4	4	4	(4)	(4)
Budget Auth.	\$566		\$447		(\$477)	
FNS:						
Professional	35	34	35	34	35	34
Clerical	10	10	10	19	11	11
Budget Auth.	\$2,550		\$2,550		\$2,600	
HNIS:						
Professional	8	8	9	9	10	10
Clerical	2	2	3	3	3	3
Budget Auth.	\$473		\$544		\$565	
EMS /2:						
Professional	37	35	36	34.9	31	31.4
Clerical	8	8	8	8	7	6.8
Budget Auth.	\$2,487		\$2,450		\$2,272	
WAOB:						
Professional	1	1	1	1	1	1
Clerical	0	0	0	0	0	0
Budget Auth.	\$60		\$62		\$64	
FS:						
Professional	468	468	359	359	346	346
Clerical	111	111	235	235	220	220
Budget Auth.	\$20,286		\$21,201		\$20,580	
TOTAL:						
Professional	937	929	837	818	817	803
Clerical	216	211	343	346	330	328
Budget Auth.	\$53,521		\$54,670		\$54,207	

/1 In 1994, ACS estimates are included in FmHA/RDA.

/2 Supports ERS, NASS, OE, OAS, and EAS.

RESOURCES AND STAFF LEVELS OF OFFICE OF COMMUNICATIONS' AREAS

Mr. DURBIN. Services of the new Office of Communications will be provided through five areas: administration; public liaison, information planning, and placement team; creative services center; and coordination and oversight team. Please provide a brief description of each area, including resources and staff levels.

Response. Administration—The administrative team is responsible for the budget, as well as all other resource management functions of OC. OC administration serves as USDA's central coordinating unit for the Freedom of Information Act—FOIA—and its amendments—Privacy Act and Computer Matching and Privacy Protection Act. Department regulations and guidelines are updated to conform with amendments to the law or new directives from the Department of Justice and Office of Management and Budget. A Data Integrity Board, required by the Computer Matching Act of 1988 was established and is presently chaired by the Director of OC. There are 37 staff years in this area and resources totaling \$3,238,427.

Public Liaison—Public Liaison—PL—develops and maintains liaison with farm, trade, consumer associates, national resources and environmental groups, educational groups, as well as with organizations representing women and minorities. PL also plans and coordinates policy and educational briefings in Washington, D.C. and across the country. PL participates in national meetings, conferences, and programs to provide and disseminate information about USDA and its programs. In working with a diverse range of constituents, agriculture and interest groups, PL acts as a clearinghouse to keep USDA agencies apprised of issues and concerns voiced by outside groups. There are 13 staff years in this area and resources totaling \$782,292.

News, Information Planning and Placement Team—The News, Information Planning and Placement Team—NPP—works on special projects such as Annual Report, Factbook on Agriculture, etc., as well as planning and placement of daily stories to targeted media markets. This team brings all production media into the news and information discussion while designing the best news and information product. NPP serves as the department level clearinghouse for providing the media with current information about USDA's programs and policies in the form of news releases, news and photo features, background statements, speeches, report summaries, and similar materials. NPP maintains continuous communication with reporters, writers, editors, radio/TV broadcasters, producers and specialized journalists. NPP monitors the activities of associations and organizations to assure appropriate information is available to USDA officials, and assists in the preparation of briefing information for the White House and the Secretary of Agriculture. There are 10 staff years in this area and resources totaling \$606,495.

Production and Creative Service Center—The Production and Creative Service Center—PCSC—includes OC's Department level design, photography, video and radio, teleconferencing, and printing functions. These areas include producing exhibits, publications, and video projects from conception through to completion, such as planning, scheduling, construction, design, layout, and editing. OC's PCSC assists the agencies in fulfilling their mission to provide information to the public on their programs. There are 69 staff years and resources totaling \$2,770,110.

Coordination and Oversight Team—The Coordination and Oversight Team—COT—includes the communication coordinators and the review functions. OC's review team separates the creative work of OC from the oversight work, while reviewing, and overseeing the news and information products of the agencies for editorial content, design, and video production. During fiscal year 1993, OC established at the Under/Assistant Secretary levels, 7 Communication Coordinator positions. These individuals provided information support and coordination functions, vertically and horizontally with all other USDA information support levels. Communication Coordinator positions were advertised department-wide and filled by career employees on a competitive basis. There are 12 staff years in this area and resources totaling \$962,676.

COMMUNICATION COORDINATOR POSITIONS

Mr. DURBIN. The Explanatory Notes state that during fiscal year 1993, seven Communication Coordinator positions were established at the Under/Assistant Secretary level. Would you please provide more detailed information on these positions including job descriptions and grade levels.

Response. There are seven communication coordinator positions. Six communication coordinator positions serve the following program mission areas: 1. Farm and International Trade Services; 2. Food, Nutrition and Consumer Services; 3. Rural Economic and Community Development; 4. Marketing and Inspection Services; 5. Natural Resources and Environment; and 6. Research, Education and Economics;

and the seventh coordinates the communications needs of Departmental Administration, Office of Inspector General, Chief Financial Officer, and other Departmental staff offices. The seven positions were announced at the GS-1035-14/15 level, with the competitive selection process resulting in four selected at the GS-15 level and three at the GS-14 level—all USDA career public affairs specialists. A copy of the position description follows:

Office of Communications
Public Affairs Specialist
GM-1035-14
Communications Coordinator

I. INTRODUCTION

The Office of Communications is responsible for developing and disseminating information for the U.S. Department of Agriculture.

The incumbent serves as a Coordinator for the communications and public affairs programs within USDA, with responsibility for planning, designing, and executing programs to inform and educate the general and specialized public concerning USDA's programs, activities, and services.

II. DUTIES AND RESPONSIBILITIES

- Participates with key USDA Officials in formulating the general information policies and programs of the Department of Agriculture.
- Serves as a Consultant and Advisor to the Under/Assistant Secretaries on matters relating to National and International information and public relations aspects of proposed policies and programs.
- Serves as a Mediator for conflict resolution between Agency information staffs assigned to the Under/Assistant Secretaries and OOC production units; assists in coordinating strategic planning and crisis management that cut across Agency lines.
- Evaluates the effectiveness and efficiency of internal information programs, media relations, and community relations programs in achieving a greater understanding of the Department's mission and programs.
- Establishes and maintains effective relationships with National News Media Representatives, Trade Associations, and Educational Communicators who monitor and report on the Department's programs.
- Provides the Under/Assistant Secretaries with information support and coordination functions, vertically and horizontally, with all other USDA information support levels.
- Maximizes opportunities for Public Outreach through media contacts and on-site visits to USDA programs when Under/Assistant Secretaries are in travel. Facilitates the clearance of news releases at the Departmental level.
- Evaluates information problems encountered in communicating the Department's programs; advises and recommends to the Under/Assistant Secretaries specific information activities designed to meet these problems.
- Monitors the effectiveness and impact of communication plans and advises management if efforts should be discontinued, emphasis changed, or coverage expanded in improving communication between the Department and its targeted audiences.

- Locates and coordinates feedback necessary for Under/Assistant Secretaries to respond promptly and accurately to media inquiries about Department's programs, policies, and activities.

III. FACTORS

1. Knowledge Required by the Position Level 1-8 1550 pts.

Mastery of communication principles, practices, methods, and techniques to function as a technical specialist on complex communication problems, issues, and in generating and evaluating information programs.

Skill in advising Under/Assistant Secretaries and other key departmental officials on communication ramifications of Departmental policies and decisions.

Skill in facilitating as spokesperson before national media representatives, often explaining complex programs and controversial issues. Digests complex technical information and uses communication skills to interpret for general audiences and to gain public understanding and acceptance.

Skill in evaluating the effectiveness of Departmental programs through mobilization of information resources to include personal contacts, media liaison, monitoring of printed and electronic media and preparation of detailed analyses upon which Departmental officials can take action to make program adjustments in the public interest and to increase efficiencies.

2. Supervisory Controls Level 2-5 650 pts.

The Director of Communications, provides administrative direction to the incumbent in terms of broadly defined departmental missions. The incumbent independently plans, designs, and executes the communication programs supporting the Department of Agriculture. The employee is expected to develop programs, determine the methods to be used, approaches to be taken, resolve conflicts, and to coordinate the work with Departmental officials.

Finished products are considered technically authoritative and often are used as tools by all officials of the department to represent definite points of view. Works is always accepted as professionally correct and minor changes are usually the result of unforeseen political considerations. Effectiveness of programs are based upon public understanding and acceptance, and measured by media feedback, letters, and verbal reports.

3. Guidelines Level 3-4 450 pts.

Guidelines are in the form of departmental policies and precedents contained in directives, which are broadly stated and of limited use in applying to situations encountered by the employee. The specialist must exercise judgment in deviating from the traditional methods that may be available, to developing new methods as required.

4. Complexity Level 4-5 325 pts.

Assignments include planning, designing, and executing, communications program involving the development of written materials to convey information about the Department's programs, the maintenance of an effective working relationship with the specialized groups, and the developing recommendations to improve program effectiveness.

The degree of professionalism in news releases, publications, backgrounders, and oral statements determine whether or not the Department's actions are understood, and directly influence the success or failure of the Department's programs and functions. Many of the projects or studies are pursued on a concurrent basis, but all generally involve the establishment of new or the refinement of existing methods and concepts.

5. Scope and Effect Level 5-5 325 pts.

The purpose of the work is to coordinate the flow of information about USDA's programs throughout the Department; to mediate conflict arising from OOC-agency interaction; to provide cross-cutting coordination in crisis/emergency situations; to determine reasons for the public's negative view of the Department's work; and to develop new or alternative means of providing information that will enhance the public's understanding of and support for the Department's programs and efforts.

6. Personal Contacts Level 6-4 110 pts.

Contacts are with nationally-known members of the media, to include network producers and reporters, wire-service writers, and major newspaper journalists. Routine contacts also include Departmental and Agencies' national, regional and local information staffs; industry and consumer groups; State and local organizations; and national leaders who have an interest in the impact the Department's programs have on their areas.

7. Purpose of Contacts Level 7-4 220 pts.

The purpose of the contacts are to advise top level officials of the Department-- on problems involved in communicating information to the affected publics; with the new media and national organizations interested in the Department's programs to explain and defend the programs, functions and performance in these varied areas against undue criticism.

8. Physical Demands Level 8-1 5 pts.

The work requires a minimum of physical exertion.

9. Work Environment Level 9-1 5 pts.

The work is performed in an office setting.

Total Points - 3640= GM-14

Office of Communications
 Office of the Director
 Public Affairs Specialist, GM-1035-15
 Communications (Media) Coordinator

I. INTRODUCTION

The Office of Communications is responsible for developing and disseminating information for the U.S. Department of Agriculture.

The incumbent serves as a Coordinator for the communications and public affairs programs within USDA, with responsibility for planning, designing, and executing programs to inform and educate the general and specialized public concerning USDA's programs, activities, and services.

II. DUTIES AND RESPONSIBILITIES

- Participates with key USDA Officials in formulating the general information policies and programs of the Department of Agriculture.
- Serves as a Consultant and Advisor to the Under/Assistant Secretaries on matters relating to National and International information and public relations aspects of the proposed policies and programs.
- Serves as a Mediator for conflict resolution between Agency information staffs assigned to the Under/Assistant Secretaries and OOC production units; assists in coordinating strategic planning and crisis management that cut across Agency lines.
- Evaluates the effectiveness and efficiency of internal information programs, media relations, and community relations in achieving a greater understanding of the Department's mission and programs.
- Establishes and maintains effective relationships with National News Media Representatives, Trade Associations, and Educational Communicators who monitor and report on the Departments programs.
- Provides the Under/Assistant Secretaries with information support and coordination functions, vertically and horizontally, with all other USDA information support levels.
- Maximizes opportunities for Public Outreach through media contacts and on-site visits to USDA programs when Under/Assistant Secretaries are in travel. Facilitates the clearance of news releases at the Department level.

- Evaluates information problems encountered in communicating the Department's programs; advises and recommends to the Under/Assistant Secretaries specific information activities designed to meet those problems.
- Monitors the effectiveness and impact of communication plans advises management if efforts should be discontinued, emphasis changed, or coverage expanded in improving communication between the Department and its targeted audiences.
- Locates and coordinates feedback necessary for Under/Assistant Secretaries to respond promptly and accurately to media inquiries about the Department's programs, policies, and activities.
- Provides equal opportunity in employment for all subordinates, applicants, and new hires, prohibits discrimination in employment based on race, color, religion, sex, national origin, age or handicap condition; and promotes a full realization of equal employment through continues affirmative actions within the work environment.

III. FACTORS

1. Knowledge Required by the Position Level 1-9 1850 pts.

Knowledge of advanced communication principals, practices, methods, and techniques to function as a Departmental technical expert on all complex communication problems, issues, and in developing and evaluating information programs.

Skill in advising Under/Assistant Secretaries and other key departmental officials on communication ramifications of Departmental policies and decisions.

Skill in facilitating as spokesperson before national media representatives, often explaining complex programs and controversial issues. Digests complex technical information and uses communication skills to interpret for general audiences and to gain public understanding and acceptance.

Skill in evaluating the effectiveness of Departmental programs through mobilization of information resources to include personal contacts, media liaison, monitoring of printed and electronic media and preparation of detailed analyses upon which Departmental officials can take action to make program adjustments in the public interest and to increase efficiencies.

2. Supervisory Controls Level 2-5 650 pts.

The Director of the Office of Communications, provides administrative direction to the incumbent in terms of broadly defined department missions. The incumbent independently plans, designs, and executes the communication programs supporting the Department of Agriculture. The employee is expected to develop programs, determine the methods to be used, approaches to be taken, resolve conflicts, and to coordinate the work with the Departmental officials.

3. Guidelines Level 3-5 650 pts.

Guidelines are broadly stated Departmental regulations, policy statements, statutory mandates, and state-of-the-art communication systems. The incumbent must exercise judgment and ingenuity in deviating from the traditional methods that may be available, adapting and developing new methods are required. As a technically recognized expert, the employee conceives new projects or studies to advance the state-of-the-art for communicating the Department's programs.

4. Complexity Level 4-6 450 pts.

The incumbent's assignments involve the full range of planning, designing, executing, and evaluating the communications program involving the development of written materials to convey intricate information about the Department's programs, the maintenance of an effective working relationship with specialized groups, and the development of recommendations to improve program effectiveness. The incumbent serves as the vital communications link between top department officials and the nation.

The incumbent's competency and degree of professionalism in news, releases, publications, backgrounders, and oral statements determine whether or not the Department's action are understood, and directly influence the success or failure of the Department's programs and functions. Many of the projects or studies are pursued on a concurrent basis, but all generally involve the establishment of new or the refinement of existing methods and concepts.

5. Scope and Effect Level 5-5 325 pts.

The purpose of the work is to coordinate the flow of information about USDA's programs throughout the Department; to mediate conflict arising from OOC-agency interactions; to provide cross-cutting coordination in crisis/emergency situations; to determine reasons for the public's negative view of the Department's work; and to develop new or alternative means of providing information that will enhance the public's understanding of and support for the Department's programs and efforts.

6. Personal Contacts Level 6-4 110 pts.

Contacts are with nationally known members of the media, to include network producers and reporters, wire-service writers, and major newspaper journalists. Routine contacts also include Department and Agencies' national, regional and local information staff; industry and consumer groups; State and local organizations; and national leaders who have an interest in the impact the Department's programs have on their areas.

7. Purpose of Contacts Level 7-4 220 pts.

The purpose of the contacts are to advise top level officials of the Department--on problems involved in communicating information to the affected public; with the new media and national organizations interested in the Department's programs to explain and defend the programs, functions and performance in these varied areas against undue criticism.

8. Physical Demands Level 8-1 5 pts.

The work requires a minimum of physical exertion.

9. Work Environment 9-1 5 pts.

The work is performed in an office setting.

Total Points - 4265= GM-15

INTERGOVERNMENTAL AFFAIRS RESPONSIBILITIES

Mr. DURBIN. All of the authorities, responsibilities, and functions assigned to the Office of Public Affairs were transferred to the Office of Communications except for Intergovernmental Affairs. Where are these responsibilities being carried out? What is the level of resources, in both dollars and staff, devoted to Intergovernmental Affairs in fiscal year 1994? Will this level be transferred to continue these responsibilities?

Response. At the present time, the Office of Intergovernmental Affairs—OIA—remains a part of OC, however the Department plans to transfer all of OIA's authorities, responsibilities and functions to the Office of Congressional Relations. The fiscal year 1994 level of resources is \$475,000 and six staff years. It is my understanding that the commitment will remain the same when OIA is transferred under the Office of Congressional Relations.

Mr. DURBIN. The 1995 budget request includes a reduction of \$580,000 in support of the President's Executive Order mandating a reduction in Federal employment. The justification of increases and decreases state that the office is reducing employment from the fiscal year 1993 base by six percent, yet the staff year levels show a higher level of employment in fiscal year 1995 than fiscal year 1993. How are you meeting the President's Executive Order? How did you arrive at the \$580,000 amount?

Response. We have met the requirement of the President's Executive Order through the use of the buyout.

The \$580,000 amount was arrived at based on the percentage of the reduction required in fiscal year 1995. The fiscal year 1995 staff year level is a six percent reduction in employment from the fiscal year 1993 base which was 150 staff years. The actual staff year usage was 132 staff years. The \$580,000 consists of three GM/GS-15's, two GM/GS-14's, one GS-12, and three GS-5's.

CONSOLIDATION OF STAFF UNITS

Mr. DURBIN. As part of your streamlining efforts you propose to restructure the office from nine major staff units to three units. Please describe the functions of each of the nine units and tell us how they will be consolidated into three units.

Response. That was an early proposal. After careful review with both our internal and external customers, we are moving towards a "flattened" communications organization of six areas within the three centers and one administrative unit. The original Office of Public Affairs, before the transition began, had nine program units and one administrative/information technology unit. They were:

1. News Division—edited, cleared and disseminated news releases, statements, positions papers, and other public documents to the press; provided liaison with the newswire services and printed media, including agricultural news organizations; handled news conferences for the Secretary and subcabinet level officials; and provided information feedback to top level officials, primarily through a daily news digest called "AG a.m."

2. Radio & Television Division—prepared and disseminated audio taped programs to radio stations and networks and video taped programs to television stations and networks; provided liaison with broadcasting stations and networks, including farm broadcasters' association; taped interviews and news conferences of the Secretary and subcabinet level officials.

3. Design Division—a Working Capital Fund—WCF—unit is a centralized design and exhibit service for the Department. Its responsibility is to give design leadership to USDA's information programs, through print, exhibits, and other media. The guiding principle of this WCF operation is to provide appropriate visual communication materials for specifically targeted audiences, clear message-related images at reasonable costs. The unit has a full complement of state-of-the-art electronic work stations, applications, sign-maker, scanners, and printers.

4. Publishing Division—is the central office for policy review and final clearance of Department publications, intended for use by the general public.

5. Printing Division—serves as the central printing procurement office in USDA and provides overall leadership and coordination for the Department's printing, composition, and related activities. It also serves as the central Office and the Congressional Joint Committee on Printing.

6. Photography Division—maintains an extensive centralized USDA Photo Library of captioned black/white prints and color slides. These images are the photo history of USDA's programs and activities. They cover subjects relating to food production, distribution, nutrition, marketing, food safety and inspection, conservation, and research. Photography also provides photographic research services and distributes photographs to the news media and to the public.

7. Video & Teleconference Division—a WCF unit has been the leader for several years for the Department, as well as other Federal agencies in evaluating and testing of teleconferencing technology and methods. Video has a wide spectrum of teleconferencing tools from audio, to compressed video through telephone lines, to interactive teleconferencing with the use of satellite technology.

The Video & Teleconference Division handled 530 orders for video productions and related services in FY 1993. Major video productions include such topics as the advantages of purchasing crop insurance, helping co-op members select well qualified directors, and training help for the boll weevil eradication program in the South.

8. Public Liaison Office—Develops and maintains liaison with farm, trade, consumer associations, national resource and environmental groups and with organizations representing women, minorities, and educational groups. PL also plans and coordinates policy and education briefings in Washington, D.C. and across the country. PL participates in national meetings, conferences, and programs to provide and disseminate information about USDA and its programs. In working with a diverse range of constituents, agriculture and interest groups, PL acts as a clearinghouse to keep USDA agencies apprised of issues and concerns voiced by outside groups, many of whom have never before participated in USDA programs.

9. Resource Management and Information Technology—provided administrative support for the agency. Included in these services were budget, procurement, personnel, and travel functions, as well as providing computer services.

The News Division and the Public Liaison Office were consolidated into the News, Information Planning and Placement Team. The Radio & Television, Design, Printing, Photography, and Video & Teleconferencing Divisions were consolidated into the Production and Creative Service Center. The Publishing Division became part of the Coordination and Oversight Team.

UPGRADING OF COMMUNICATIONS EQUIPMENT

Mr. DURBIN. The budget request for fiscal year 1995 includes an increase of \$198,000 for upgrading communications equipment. Please provide a detailed breakout of how this request will be used. What is the savings that will result from the purchase of this equipment?

Response. The requested \$198,000 will be used for the expansion and upgrade of computer and communication equipment such as:

1. A computer Bulletin Board serving all USDA's customers—The Office of Communication Bulletin Board System will enhance and give easy access to information disseminated to our customers.

2. Fax-on-Demand Technology—OC plans to expand, as well as upgrade the present AgNewsFax system. This will allow OC to increase the volume of information available to customers. Finally, improving service to existing customers goes beyond simply making more information available. Different customers have different needs, therefore OC will create a communications system that is responsive to all of our customers needs.

3. Expanding OC local area network system to allow OC to use a wide-area network to "talk" to all of USDA.

OFFICE OF COMMUNICATIONS—OTHER SERVICES BY SUB-OBJECT CLASS

Mr. DURBIN. Provide a subobject class breakout for object class 25, other services, for fiscal years 1993 through 1995.

[The information follows:]

(Dollars in thousands)

Sub-object class		1993	1994	1995
2500	Other Services	\$27	\$8	\$8
2510	Contractual Services Performed by Other Federal Agencies	533	166	163
2520	Related Expenditures	68	21	21
2530	Repair, Alterations or Maintenance, Furniture or Structures	32	10	10
2540	Contractual Services—Other	92	28	28
2550	Agreements—Other	94	29	29
2560	OIRM Computer Services Unit	40	12	12
2570	Miscellaneous Services	49	15	15
2580	Fees	5	2	1
Total		940	291	287

VIDEO PRODUCTION

Mr. DURBIN. One of the productions developed by the Video and Telecommunications Division was a video on the advantages of purchasing crop insurance. How much did it cost to produce this video, how many copies were distributed, and who was the receiver of this information?

Response. Our Video Unit produces video products for all USDA's agencies. The video "Crop Insurance: Risk Management for the 90's" was produced at a WCF cost of \$51,020. To date, 1,000 copies have been distributed to insurance industry co-operators, Extension Service users and others who impart information to farmers and ranchers. This video was part of a Federal Crop Insurance Corporation outreach effort.

Mr. DURBIN. How do you evaluate the effectiveness of such productions?

Response. The video was produced to draw attention to the availability of crop insurance, and to give a quick overview of the advantages of owning crop insurance. The effectiveness of the video is measurable by how many of those exposed to the video at 198 fairs and other agricultural events over the past year, have, in fact, asked questions inspired by the video. Many have also asked for further information in the form of brochures, which explain the program in detail.

OFFICE OF COMMUNICATIONS' PHOTO LIBRARY

Mr. DURBIN. The Office of Communications maintains an extensive centralized USDA Photo Library of captioned black/white prints and color slides. Why isn't this collection located at the National Agricultural Library?

Response. The USDA Central Photo Library, located within the Photography Unit of the Office of Communications, is an active file of mostly original material. The library serves the public affairs function of the Department of Agriculture's many agencies, as well as the Department itself. The Central Library is an adjunct to the work of the Photojournalism section in the Photography Unit, as well as its Reproduction and Review section.

The collection is not located at the National Agricultural Library—NAL, because it is an active file of original material. Therefore, its proximity to the prime users of that material is of great importance. Researchers, photojournalists, and reproduction and review staff members regularly respond to demands for material for news releases, and for placement of their photographs. The Central Photo Library also answers requests from the general public. Again proximity plays an important role.

It is important to note that the Photography Unit in partnership with the NAL has produced a laser disk containing some 15,000 of the best photographs from the USDA Central Photo Library. A copy of that disk is available at NAL and is an excellent photo research tool allowing quick and thorough research while preserving the originals in the Central Photo Library's climate controlled storage area.

SURVEY ON WHERE AMERICAN FARMERS GET THEIR INFORMATION

Mr. DURBIN. Your office requested a survey from the National Agricultural Statistics Service to determine where American farmers get their information about USDA programs and other needed information. Please give us a brief description of the results of this survey and provide a copy of the Executive Summary for the record.

Response. Some of the results of this survey were as follows:

1. Approximately 82 percent of the respondents indicated that other farmers and ranchers were most often the sources receiving information about USDA programs;
2. Approximately 76 percent of the respondents indicated familiarity with the Food Stamp program, followed by the School Breakfast and Lunch programs at 73 percent;
3. Federal Crop Insurance, at 65 percent, was the most recognized farm program;
4. The county Agricultural Soil Conservation Service newsletter was reported as being received by 77 percent of the respondents; and Farm Cooperatives was an instant second at 25 percent;
5. Sixteen percent of farm operators reported, that they used computers. Reports of computer usage ranged from 13 percent in the South to 33 percent in the West;

6. Approximately 32 percent of the respondents indicated they would use a USDA computer bulletin board if one were available; and

7. Approximately 72 percent of the farm operators indicated they would use a toll free number to obtain farm information.

A copy of the Executive Summary follows:

1993 OPA FARMER INFORMATION SURVEY

HIGHLIGHTS

A Farmer Information Survey was conducted by the National Agricultural Statistics Service (NASS) for the Office of Public Affairs (OPA, USDA). The survey results will provide the basis from which decisions can be made to improve the USDA information marketing process.

The survey results were summarized into four geographic regions, as follows:

Northeast:	CT, MA, ME, NH, NJ, NY, PA, RI, and VT.
South:	AL, AR, DE, FL, GA, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA, and WV.
Midwest:	IA, IL, IN, KS, MI, MN, MO, NE, ND, OH, SD, and WI.
West:	AK, AZ, CA, CO, HI, ID, MT, NV, NM, OR, UT, WA, and WY.

The Idaho and Mississippi NASS State Statistical Offices (SSOs) printed, labeled, and mailed the questionnaires, and conducted nonresponse telephone follow-up. The Mississippi SSO contacted the Northeast and South regions while the Idaho SSO contacted the Midwest and West regions.

The Sample

A simple stratified random sample was selected from all active records on the NASS List Sampling Frame with at least one acre of land. Records identified as agri-businesses were excluded. The sample was stratified based on locality. The sample size at the national level totaled 5,321.

Data Collection

The questionnaire and cover letter were mailed on August 11, 1993 and a reminder letter was mailed on August 19. Those who had not yet responded by mail were contacted by telephone August 23-30. Approximately 50 percent of the sample participated in the survey. Of the 2,660 responses, 34 percent came from the original mail survey and the other 66 percent came from the telephone follow-up.

Survey Results

Demographic characteristics were summarized for each region and the U.S. using the total usable reports. The Northeast and West regions were oversampled in order to obtain valid regional estimates. Regional indications were adjusted to remove this overrepresentation when calculating the U.S. percentages. The estimated number of farms within each region were used to make this adjustment.

Sources of Farm Information

Respondents were asked to identify their sources of farm information. Approximately 82 percent of the respondents indicated that other farmers and ranchers were the most often utilized source of information. Ag magazines, journals, or newsletters, and daily or local newspapers, at 71 and 72 percent, respectively, were identified as the second and third most common information sources. Television, at 68 percent, and radio, at 64 percent, round out the top five farming information sources.

The following USDA agencies were reported as being used as farm information sources:

Agricultural Stabilization and Conservation Service (ASCS), personal visit	54 percent
ASCS, telephone	36 percent
Cooperative Extension Service	48 percent
USDA publications	32 percent
Farmers Home Administration	10 percent

USDA Programs

Respondents were asked if they participated in, knew the provisions of, or had heard about different USDA programs. Respondents who indicated they participated in, or knew the provisions of a program were also credited as having heard about the program.

Approximately 76 percent of the respondents indicated familiarity with the Food Stamp Program, followed by the School Breakfast and Lunch Programs at 73 percent. Federal Crop Insurance, at 65 percent, was the most recognized farm program. The Conservation Reserve Program and Agriculture Conservation Program were recognized by 60 percent of the respondents, followed closely by the Acreage Reduction Program at 59 percent. The Special Milk Program for Children was also recognized by 59 percent of the respondents.

Computer Usage

Across the U.S., about one-fourth of the farm operators reported owning a computer, but only 16 percent reported using their computer for farm-related activities. Reports of computer usage ranged from 13 percent in the South to 33 percent in the West. Not surprisingly, the more education farm operators had, the more likely they were to own or use a computer.

Across the U.S., 32 percent of the respondents indicated they would use a USDA computer bulletin board if one were available. This is higher than the percent of farm operators who own a computer because an operator could use a computer at a County Extension Office or another location to access the bulletin board.

Toll Free Number

Seventy-two percent of the farm operators indicated they would use a toll free number to obtain farm information. Response across regions ranged from 68 percent in the West to 74 percent in the South.

USDA Publications

Respondents were asked to indicate if they had received a USDA publication during the last three years regarding:

- farming practices,
- farm programs,
- finance programs,
- food and nutrition programs, or
- international farm programs.

Across the U.S., 40 percent of the respondents had received a USDA publication about farm programs. This ranged from 29 percent in the West region to 49 percent in the Midwest. This difference is expected since fewer operations in the West qualify for USDA programs.

Approximately one-third of the respondents had received a USDA publication about farming practices, ranging from 29 percent in the West to 35 percent in the Midwest.

Far fewer respondents had received publications about finance programs, food and nutrition programs, or international farm programs. Only 12 percent had received a publication about finance programs. Seven percent had received a publication about food and nutrition programs, while only four percent had received a publication about international farm programs.

Respondents were asked to indicate which USDA periodicals or newsletters they received or had heard of. The County ASCS Newsletter was reported as being received by 77 percent of the respondents. Farm Cooperatives was a distant second at 25 percent. Agricultural Outlook was received by 21 percent of the respondents, followed by Agricultural Research, at 19 percent, and Livestock and Poultry Update, at 18 percent. All other publications were reported at 10 percent or less.

Occupation

Approximately 75 percent of the respondents reported they were farm operators, 23 percent reported their major occupation was non-farm work, and two percent reported their occupation as hired managers.

Age of Operator

Almost half the respondents were between 45 and 65 years old. The South and West had higher percentages of farm operators 65 years or over.

Highest Level of Formal Education

Twenty-one percent of the respondents had a college degree, while 46 percent had some education beyond high school. Operators in the West had higher levels of education while those in the South had lower levels.

Gross Value of Sales

Forty-seven percent of the respondents reported gross value of sales less than \$10,000, 36 percent between \$10,000 and \$99,999, and 17 percent \$100,000 or more. Fifteen percent of the respondents did not qualify as farms under the NASS definition, as their gross value of sales were less than \$1,000. These operations were therefore excluded from the results.

Commodity of Major Source of Farm Income

Forty-one percent of the respondents reported livestock as their major source of farm income. Cash grains were the major source of farm income for 18 percent of the respondents. Nine percent of the respondents identified themselves as dairy operations, 8 percent as fruit or vegetable producers, and four percent as tobacco producers. The remaining respondents reported some other type of farming operation, which would include nurseries and greenhouses, christmas tree farms, cotton producers, etc.

BULLETIN BOARD SYSTEM

Mr. DURBIN. You are in the process of designing a bulletin board system that will allow the public access to information. How will this system differ from the AgNewsFax system?

Response. The bulletin board system will differ from the AgNewsFax system by allowing a different segment of the public computer users to access information by computer about USDA, its publications, news releases, etc., and to download this information into a computer file which can be stored electronically. The bulletin board system can be searched for specific mission area information.

The bulletin board system is one of the many technology tools that will allow OC to get information to the public in a timely manner, and responds to specific needs of the USDA customer.

JOINT U.S./RUSSIA PUBLICATION ON SOIL AND WATER CONSERVATION

Mr. DURBIN. What is the status of the joint publication between the Russian Academy of Agricultural Sciences and the Soil Conservation Service on soil and water conservation? When can we expect to see this publication?

Response. Contracting is underway to have the Russian articles translated into English. After this is done, all the material will be reviewed for completeness and the text will be contracted for typesetting. If all goes smoothly, we could be ready for printing by early fiscal year 1995.

DATA INTEGRITY BOARD

Mr. DURBIN. What is the function of the Data Integrity Board?

Response. The function of the Data Integrity Board, which Ms. Webb presently chairs, is to coordinate and oversee agency activities in implementing the Computer Matching and Privacy Protection Act. This was done to establish certain safeguards for the sharing of information between agencies in conducting computer matching programs. The purpose of the Act is to ensure the integrity, privacy, and verification of data used in computerized exchange operations. The purpose of such data exchanges is to compare information in an effort to reduce fraud, waste, and abuse in Federal programs.

TECHNOLOGY MODERNIZATION EFFORTS

Mr. DURBIN. What is the status of your technology modernization efforts?

Response. To date OC has drafted a technical as well as a functional design document that gives the specification for the Bulletin Board System. OC's IRM staff is reviewing all computer configurations as well as analyzing the present LAN system to prepare for a system upgrade. OC continues to survey its Fax users and evaluate the cost efficiency as well as the technological direction for upgrade that will address our customers' needs.

NATIVE AMERICAN PROGRAM

Mr. DURBIN. In fiscal year 1993, \$182,000 or about 38 percent of the total budget for Intergovernmental Affairs was expended on the Native American program. What is this amount for fiscal year 1994.

Response. The estimated amount to be spent on the Native American Program for fiscal year 1994 is \$130,000.

PRESS RELEASES

Mr. DURBIN. Please update the table that appears on page 672 of last year's hearing record showing the number of press releases issued by your office to include fiscal year 1993.

[The information follows:]

Number of news releases issued by the Office Of Communications

<i>Calendar years 1986-93</i>	<i>Number</i>
1986	1,300
1987	1,616
1988	1,720
1989	1,688
1990	1,693
1991	1,442

	<i>Calendar years 1986-93</i>	<i>Number</i>
1992	1,366
1993	1,068

MEDIA SERVICES

Mr. DURBIN. Were any new media services provided in fiscal year 1993? Were any previous services deleted?

Response. There weren't any new media services provided in fiscal year 1993. Previous services were not deleted.

REIMBURSEMENTS TO OC FROM OTHER USDA APPROPRIATIONS

Mr. DURBIN. Update the table that appears on page 671 of last year's hearing record showing reimbursements from other USDA agencies to include fiscal year 1993 actuals.

[The information follows:]

REIMBURSEMENTS TO OC FROM OTHER USDA APPROPRIATIONS
(In thousands of dollars)

	1990	1991	1992	1993	1994	1995
Agricultural Cooperative Service.....	32	76	64	105	67	68
Agricultural Marketing Service.....	139	87	105	123	108	111
Agricultural Research Service.....	357	387	466	395	514	550
Agricultural Stabilization and Conservation Service....	413	81	223	170	196	176
Animal and Plant Health Inspection Service.....	946	286	366	545	368	377
Cooperative State Research Service.....	31	103	110	105	111	113
Departmental Administration.....	99	134	77	116	84	86
Economics Management Staff.....	19	78	57	37	58	59
Economics Research Service.....	75	53	47	42	42	42
Extension Service.....	60	137	149	169	143	146
Farmers Home Administration.....	184	313	293	274	297	304
Federal Crop Insurance Corporation.....	9	3	82	160	81	82
Federal Grain Inspection Service.....	16	29	7	66	6	6
Food and Nutrition Service.....	406	231	428	290	419	431
Food Safety Inspection Service.....	126	199	204	235	193	196
Foreign Agricultural Service.....	258	205	183	154	168	170
Forest Service.....	439	977	1291	1151	1311	1323
Graduate School.....	2	4	0	3	0	0
Human Nutrition Information Service.....	17	39	35	33	36	36
National Agricultural Library.....	15	52	50	44	50	50
National Agricultural Statistics Service.....	10	7	12	10	7	8
Office of Budget and Program Analysis.....	4	6	5	7	8	8
Office of Public Affairs.....	231	361	329	302	276	282
Office of the Inspector General.....	9	18	40	47	38	39
Office of International Cooperation and Development.....	10	9	6	6	8	8
Office of the General Counsel.....	17	8	8	11	11	11
Office of the Secretary.....	34	40	35	53	67	68
Office of Transportation.....	4	10	0	0	0	0
Packers and Stockyards Administration.....	4	4	11	10	10	10
Rural Development Administration.....	0	0	0	14	3	3
Rural Electrification Administration.....	20	20	15	14	13	13
Science and Education Administration.....	8	7	0	0	0	0
Soil Conservation Service.....	513	578	436	358	405	415
World Agricultural Outlook Board.....	7	13	56	52	58	61
Non USDA.....	38	36	50	92	30	33
Total.....	4,552	4,591	5,240	5,193	5,186	5,285

USDA MATCHING AGREEMENTS

Mr. DURBIN. Under the Computer Matching and Privacy Act of 1988, USDA has entered into three matching agreements to identify employees who may owe the Federal government money. Two of these agreements, one with the Postal Service and one with the Department of Defense, are projected to save an estimated \$5.5 million. During last year's hearing Ms. Webb testified that collections to date had totaled \$727,155, but costs under the agreements were \$230,606. Please update these figures for us. When will the \$5.5 million savings be realized?

Response. Two of the three agreements are salary *offset* initiatives with the U.S. Postal Service and the Department of Defense, on behalf of ASCS, FmHA, FCIC, and OFM. The third is an agreement with the Department of Housing and Urban Development that gives lenders and agencies access to the Credit Alert Interactive Voice Response System, CAIVRS, for the purpose of prescreening loan and loan guarantee applicants for delinquency in paying a Federal debt. The costs under the agreements presently are about \$298,000. Collections under the agreements to date are over \$1,052 million. It now appears that the anticipated collections of \$5.5 million will not be realized in the very near future.

Mr. DURBIN. The third agreement, the Credit Alert Interactive Voice Response System, with the Department of Housing and Urban Development was in the beginning stages of development. What is the status of this agreement?

Response. In the Spring of 1993, the Department of Agriculture's Farmers Home Administration began reporting information on delinquencies and defaults to the Credit Alert Interactive Voice Response System database, which is maintained by the Department of Housing and Urban Development. FmHA will begin accessing the CAIVRS database for prescreening loan applicants within the next few months. FmHA has developed a proposed rule for publication in the Federal Register, and should publish the final rule shortly thereafter to enable the agency to begin accessing the prescreening capabilities.

Mr. DURBIN. In addition to these agreements, the Department was planning to enter into three more matching programs for debt collection and other purposes, all with the Food and Nutrition Service. Please tell us the status of these agreements.

Response. The three new agreements, on behalf of the Food and Nutrition Service, are salary offset programs with the Department of Defense and the U.S. Postal Service, and an electronic information program—called the Disqualified Recipient Subsystem—for recording data on individuals who have been disqualified from participation in the food stamp program. The Department of Defense agreement was signed on February 15, 1994, and became effective in March 1994. The U.S. Postal Service agreement was signed on March 23, 1994, and will become effective after publication of a matching notice in the Federal Register. The Disqualified Recipient Subsystem agreement has been entered into with FNS by all 53 of the State agencies that participate in the food stamp program. Under the agreement, States may use electronic information to assign the legally required penalty period for program violations, and for screening new applicants and current food stamp recipients to determine if they should be serving a disqualification imposed in another jurisdiction.

OFFICE OF COMMUNICATIONS BUDGET REQUESTS

Mr. DURBIN. Provide a breakout of the Office of Communication budget request to the Secretary, the Secretary's request to OMB, and the OMB allowance.

Response. The Office of Communications budget request to the Secretary was \$8,790,000, the Secretary's request to OMB was \$8,393,000 and the President's budget was \$8,360,000.

WORK PERFORMED BY CONTRACT

Mr. DURBIN. Is any work performed by this office contracted out? If so what type of work is contracted out and how many staff years are involved?

Response. No work performed by the appropriated side of OC is contracted out. However, because of the nature of the WCF units, work is contracted out on an as-needed basis.

Mr. DURBIN. What are the plans to reduce contract employees over the next five years?

Response. No work performed by the appropriated side of OC is contracted out. Therefore, OC has no plans to reduce contracted employees, however OC's WCF unit is presently reviewing its use of contract employees. This may result in a reduction.

OFFICE OF COMMUNICATIONS

Purpose Statement

The Office of Communications (formerly the Office of Public Affairs) was established by the Secretary of Agriculture on October 1, 1989, under authority contained in the Reorganization Plan No. 2 of 1953 (7 U.S.C. 2201). Secretary Espy established the Office of Communications (OC), and ordered that the Office of Public Affairs be abolished effective September 5, 1993. All of the authorities, responsibilities, and functions assigned to the Office of Public Affairs were transferred to the Office of Communications (except for Intergovernmental Affairs responsibilities). OC undertakes its public information activities under delegations of authority from the Secretary of Agriculture; and through OC's public information activities, people outside USDA learn about the policies, goals, programs, and executive management of the Department.

OC provides leadership, expertise, counsel, and coordination for the development of communication strategies which are vital to the overall formulation, awareness, and acceptance of U. S. Department of Agriculture programs and policies. OC serves as the principal USDA contact point for dissemination of consistent, timely information. OC has reduced separate units, and created an interactive team approach to communications management as a result of its internal reorganization. As of September 30, 1993, there were 125 full-time permanent employees and 17 other than full-time permanent employees.

The primary program of the Office of Communications is:

Communications and Public Affairs. Providing communications and public affairs direction in the development and delivery of useful information through all media to the public on USDA's involvement in all areas of agriculture including: farm and international trade services; rural economic and community development; food, nutrition and consumer services; natural resources and environment; marketing and inspection services; and research, education and economic activities. OC also serves as liaison between the Department and the many associations and organizations representing America's food, fiber, and environmental communication, with emphasis on policy education.

Service is provided through (5) five areas: Administration; Public Liaison; News, Information Planning, and Placement Team; Creative Services Center; and Coordination and Oversight Team. OC also provides centralized services financed through the Working Capital Fund (WCF) in the areas of video production and teleconferencing, design and exhibits production.

OFFICE OF COMMUNICATIONS

Available Funds and Staff-Years1993 Actual and Estimated 1994 and 1995

Item	1993 Actual		1994 Estimated		1995 Estimated	
	Amount	Staff Years	Amount	Staff Years	Amount	Staff Years
Direct Appropriations:	\$8,925,000	105	\$8,570,000	117	\$8,360,000	111
<u>Obligations Under Other USDA Appropriations:</u>						
Agency Photo Service	468,504	--	680,000	--	685,000	--
Agriculture Research Service . .	--	--	54,000	1	84,000	1
Administrative Support to Working Capital Fund	74,465	2	--	--	--	--
Total, Reimbursements	542,969	2	734,000	1	769,000	1
<u>Working Capital Fund:</u>						
Video & Teleconference and Visual Design Services	4,650,000	25	4,452,000	29	4,516,000	29
Total, Working Capital Fund . .	4,650,000	25	4,452,000	29	4,516,000	29
Total, Other USDA Appropriations	5,192,969	27	5,186,000	30	5,285,000	30
Total, Agriculture Appropriations	14,117,969	132	13,756,000	147	13,645,000	141
<u>Non-Federal Funds:</u>						
Sale of Photos & Slides	8,031	--	10,000	--	10,000	--
Total, Office of Communications	14,126,000	132	13,766,000	147	13,655,000	141

OFFICE OF COMMUNICATIONS

Permanent Positions by Grade and Staff-Year Summary1993 and Estimated 1994 and 1995

Grade	1993	1994	1995
	Headquarters	Headquarters	Headquarters
ES-4	2	2	2
ES-1	2	3	3
GS/GM-15	10	8	8
GS/GM-14	29	30	25
GS/GM-13	20	16	21
GS-12	14	20	18
GS-11	10	13	11
GS-9	13	17	15
GS-8	3	3	3
GS-7	16	20	20
GS-6	3	5	5
GS-5	5	4	4
GS-4	1	1	1
Upgraded Positions	5	5	5
Total Permanent Positions	133	147	141
Unfilled Positions end-of-year	-2	--	--
Total, Permanent Employment, end-of-year	131	147	141
Staff-Years: Ceiling	132	147	141

OFFICE OF COMMUNICATIONS

CLASSIFICATION BY OBJECTS

1993 and Estimated 1994 and 1995

Personal Compensation:		<u>1993</u>	<u>1994</u>	<u>1995</u>
Headquarters		\$5,375,201	\$6,357,000	\$6,056,000
11	Total personnel compensation	5,375,201	6,357,000	6,056,000
12	Personnel Benefits	840,578	1,137,000	1,044,000
13	Benefits for former personnel	1,349	13,000	13,000
Total pers. comp. & benefits		6,217,128	7,507,000	7,113,000
Other Objects:				
21	Travel	81,283	68,000	68,000
22	Transportation of things	5,599	11,000	11,000
23.3	Communications, utilities, and miscellaneous charges	459,288	342,000	340,000
24	Printing	620,096	243,000	237,000
25	Other services	940,326	291,000	287,000
26	Supplies and materials	153,673	95,000	95,000
31	Equipment	204,591	13,000	209,000
Total other objects		2,464,856	1,063,000	1,247,000
Total direct obligations		<u>8,681,984</u>	<u>8,570,000</u>	<u>8,360,000</u>
<u>Position Data:</u>				
Average Salary, ES positions		\$97,863	\$101,790	\$104,376
Average Salary, GM/GS positions		\$49,344	\$52,215	\$52,223
Average Grade, GM/GS positions		11.24	10.96	10.98

OFFICE OF COMMUNICATIONS

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

Office of Communications[Public Affairs]

For necessary expenses to carry on services relating to the coordination of programs involving public affairs, and for the dissemination of agricultural information and the coordination of information, work and programs authorized by Congress in the Department, [~~\$8,570,000~~] \$8,360,000 including employment pursuant to the second sentence of Section 706(a) of the Organic Act of 1944 (7 U.S.C. 2225), of which not to exceed \$10,000 shall be available for employment under 5 U.S.C. 3109, and not to exceed \$2,000,000 may be used for farmers' bulletins: Provided, That hereafter, none of the funds available to the Department of Agriculture may be used to produce part 2 of the annual report of the Secretary (known as the Yearbook of Agriculture).

[Intergovernmental Affairs]

[For necessary expenses for programs involving intergovernmental affairs and liaison within the executive branch. \$475,000.]

This change reflects the move of the Intergovernmental Affairs function from the Office of Communications to the Office of the Assistant Secretary for Congressional Relations.

OFFICE OF COMMUNICATIONS

Appropriations Act, 1994	\$9,045,000
Budget Estimate, 1995	8,360,000
Decrease in Appropriation	<u>-685,000</u>

Adjustments in 1994:

Appropriations Act, 1994	\$9,045,000	
Function transferred to the Assistant Secretary for Congressional Relations a/	<u>-475,000</u>	
Adjusted base for 1995		\$8,570,000
Budget Estimate, 1995		<u>8,360,000</u>
Decrease from adjusted 1994		<u>-210,000</u>

a/ Pursuant to the authority given to the Secretary in Reorganization Plan No. 2 of 1953, function of the Office of Intergovernmental Affairs was transferred to the Assistant Secretary for Congressional Relations.

SUMMARY OF INCREASES AND DECREASES

(On basis of adjusted appropriation)

Item of Change	1994 Estimated	Pay Cost	Other Changes	1995 Estimated
Communications	\$8,570,000	+\$76,000	-\$286,000	\$8,360,000

Project Statement

(On basis of adjusted appropriation)

Item of Change	1993 Actual		1994 Estimated		Increase or Decrease	1995 Estimated	
	Amount	Staff Years	Amount	Staff Years		Amount	Staff Years
Communications	\$8,681,984	105	\$8,570,000	117	-\$210,000	\$8,360,000	111
Unobligated balance	243,016	--	--	--	--	--	--
Total available or estimate	8,925,000	105	8,570,000	117	-\$210,000(1)	\$8,360,000	111
Transferred to the Asst. Secy for Cong. Rel.	+468,000	+5	+475,000	+6			
Total Appropriations	9,393,000	110	9,045,000	123			

EXPLANATION OF PROGRAM

The appropriation for the Office of Communications funds the activity established pursuant to the relevant sections of Secretary's Memorandum No. 1927, dated October 5, 1977, and the authority contained in 5 U.S.C 301 and Reorganization Plan No. 2 of 1953 (7 U.S.C. 2201). The activity carried out is as follows:

The Office of Communications provides leadership, expertise, and counsel for the development of public affairs strategies which are vital to the overall formulation, awareness, and acceptance of U.S. Department of Agriculture programs and policies. Office of Communications serves as the principal USDA contact point for dissemination of consistent, timely information.

Explanation of Proposed Reorganization: Under the Secretary's proposed reorganization plan, 5 staff years and related funding will be reassigned from the Office of Communications to the Office of the Secretary to establish an Office of the Assistant Secretary for Communications.

JUSTIFICATION OF INCREASES AND DECREASES

(1) A net decrease of \$210,000 for Communications.(a) A decrease of \$580,000 for a reduction in Federal employment costs.

Need for Change. In support of the Secretary's streamlining efforts and the President's Executive Order mandating a reduction in Federal employment, OC is reducing employment from the FY 1993 base by 6 percent.

Nature of Change. To achieve the reduction, OC will streamline its operations. The total reduction in personnel costs amounts to \$580,000. OC's streamlining includes: (1) restructuring their organization from nine major staff units to three new major units, which will require fewer unit managers; (2) reducing the Department's annual printing cost by requiring more stringent justifications for publication, design, and printing needs; and (3) conducting reviews on consolidating specialized communications services (such as photographers, video graphers, and graphics designers) from the agencies with the Office of Communications which will improve the services and reduce the cost.

(b) A decrease of \$58,000 for administrative efficiency.

Need for Change. In support of the Secretary's streamlining efforts and the President's Executive Order to reduce overhead-type outlays from the FY 1993 baseline, budget authority is reduced by \$58,000.

Nature of Change. In order to achieve these savings, OC will reduce discretionary expenses by \$58,000 in FY 1995. This will be accomplished through monitoring the level of information support products in areas such as printing and visual services, and through conducting a review of administrative support service charges.

(c) An increase of \$76,000 for pay increases.(d) An increase of \$44,000 which reflects a 2.6 percent increase in non-salary costs.(e) An increase of \$110,000 for personnel compensation.

Need for Change. This increase is needed to cover the anticipated costs of a lump sum payment for a retiring SES employee.

Nature of Change. The lump sum payment will provide \$110,000 for one SES retiree.

(f) An increase of \$198,000 for upgrading of communications equipment.

Need for Change. OC's mission is to communicate departmental information and actions about USDA's programs to many audiences. The information communicated must be current, accurate, and easily accessible. In order to achieve this, OC needs to improve and expand its communication services.

Nature of Change. Funds will be used to expand the use of modern on-line computer communications systems such as computer bulletin boards, fax-on-demand technology and a tape distribution system.

GEOGRAPHIC BREAKDOWN OF OBLIGATIONS AND STAFF YEARS
1993 and Estimated 1994 and 1995

	1993		1994		1995	
	<u>Amount</u>	<u>Staff Years</u>	<u>Amount</u>	<u>Staff Years</u>	<u>Amount</u>	<u>Staff Years</u>
Washington, D.C.	\$8,681,984	105	\$8,570,000	117	\$8,360,000	111
Unobligated balance	243,016	--	--	--	--	--
Total Available or Estimate	<u>8,925,000</u>	<u>105</u>	<u>8,570,000</u>	<u>117</u>	<u>8,360,000</u>	<u>111</u>

OFFICE OF COMMUNICATIONS

STATUS OF PROGRAMS

The Office of Communications (OC) directs information about USDA programs to the people of the United States. To achieve that objective, OC reports through the various media and sometimes directly to farmers, consumers, environmentalists, business interests, special groups, and the general public regarding the Department's programs, policies, and activities. The success of the Department's initiatives often depends on the effectiveness of public affairs programs in creating awareness.

Activities under this appropriation are carried out through the following major program areas:

NEWS, INFORMATION PLANNING, AND PLACEMENT

The News, Information Planning, and Placement Center team works on special projects (e.g., Annual Report, Factbook on Agriculture, etc.), as well as planning and placement of daily stories to targeted media markets. This team brings all production media into the news and information discussion while designing the best news and information product.

OC serves as the Department-level clearinghouse for providing the media with current information about USDA's programs and policies in the form of news releases, news and photo features, background statements, speeches, report summaries, and similar materials. OC maintains continuous communication with reporters, writers, editors, radio/TV broadcasters, producers and specialized journalists. OC monitors the activities of associations and organizations to assure appropriate information is available to USDA officials and assists in the preparation of briefing information for the White House and the Secretary of Agriculture.

In fiscal year 1993, OC delivered 1,036 news releases and related items for national distribution, with most of those materials available both on paper and through electronic dissemination and by facsimile to reach a broader section of the public with greater speed and accuracy.

OC also works closely with the Department's agencies in providing feedback to top level officials on what the popular and trade press are saying about USDA programs, policies, and actions, including preparing a daily book of news clippings and wire stories. OC staff prepares "Ag a.m.," a daily morning news digest, and news digests that summarize articles and editorials from news wires, national newspapers, news magazines and other key periodicals dealing with agricultural issues. The news digests are electronically prepared and made available electronically on the USDA LAN system, by facsimile, and in hard copy for nationwide early morning distribution to Department officials.

CREATIVE SERVICES

The Production and Creative Service Center includes OC's Department-level design, photography, video & radio, teleconferencing, and printing functions. This includes producing exhibits, publications, and video projects from conception through to completion (e.g., planning, scheduling, construction, design, layout, editing, etc.). OC's production and creative areas assists the agencies in fulfilling their mission to provide information to the public on their programs.

Electronic Media -- OC's Video and Teleconferencing Division, a Working Capital Fund (WCF) unit has been the leader for several years for the Department, as well as other Federal agencies in evaluating and testing of teleconferencing technology and methods. OC has a wide spectrum of teleconferencing tools from audio, to compressed video through telephone lines, to interactive teleconferencing with the use of satellite technology.

The Video and Teleconference Division received 530 orders for video productions and related services in fiscal year 1993. Major video productions included such topics as the advantages of purchasing crop insurance, helping co-op members select well qualified directors, training help for the boll weevil eradication program in the south, educating travelers to foreign countries about leaving behind any products which might contain pests, offering marketing services in USDA agencies such as AMS and FGIS, recruiting for OIG auditors and investigators, educating the public about the history of America's forests, delivering summer feeding programs for the needy, informing audiences through several "how to" stream and soil reclamation and conservation videos, training through mediation for FmHA employees, training through use of grain inspection standards, and educating the public through live outreach forums including farm income, nutrition, and rural development. This unit handled 2,515 audioconferences last year, which is an increase of 477 conferences over the past year's total.

Radio -- USDA's Radio Newsline provides 24-hour availability of five to ten news items, many with voice actualities, each no longer than 60 seconds. These are recorded and made available at 5 p.m. EST each weekday except holidays. Stations access the playback machines via telephone, recording the material for future use in their broadcast. Over 1,000 stories were produced by staff during fiscal year 1993. A number of agricultural networks with up to 150 affiliated stations each are regular users of this service. In addition, four weekly series are offered on audio cassette with accompanying cue sheets. These are distributed to approximately 900 radio stations and networks. Over 16,000 calls were received by the Radio Newsline in 1993.

The radio and TV staff received international recognition during fiscal year 1993 for the quality of their programming. Radio staff received a medal in the educational category at the New York Festivals International Radio Competition for a program produced and distributed in USDA's weekly cassette service. TV staff received an award at the Ecofilm Festival in the Czech Republic for the program "Managing Our National Forests". The program was distributed overseas by the United States Information Agency.

Hispanic Information Service is a weekly tape service mailed to radio stations. The service offers both audio cassette and reel-to-reel tape.

Television -- USDA television news service provides news actualities regarding Department policy and features. These are distributed by satellite (Galaxy 6) on Thursday evening and Saturday morning and repeated on Monday morning. Feature subjects cover a wide range of topics. Over 100 features and more than 450 actualities were produced by staff for this service.

"Agriculture Update," a 5-minute news format program, is produced every other week and provides information about agricultural production programs.

"Research News Features" are 2 to 3 minute programs produced on location and cover developments in such topics as agricultural research.

Photography -- OC maintains an extensive centralized USDA Photo Library of captioned black/white prints and color slides. These images are the photo history of USDA's programs and activities. They cover subjects relating to food production, distribution, nutrition, marketing, food safety and inspection, conservation, and research. OC provides photographic research services and distributes photographs to the news media and to the public.

"Photojournalism" -- OC works with USDA agencies to develop and distribute to national, regional and local media, picture stories and photographic press releases to inform the public of USDA programs, activities, and services available.

"Audio Visual Presentations" -- OC works with USDA agencies to produce and distribute narrated slide presentations on various agricultural topics and programs. These are available as slide sets or video cassettes to educational organizations, industry, and the public.

In fiscal year 1992, Photography Division completed acquisition of basic digital electronic equipment to supplement existing analog imaging equipment. In fiscal year 1993, OC implemented the digital operation system allowing satellite linkup to send images around the world in minutes. The new technology is more efficient for photographic research and offers easier access to images available in the Photographic Library.

Design -- Design, a Working Capital Fund (WCF) unit, is a centralized design and exhibit service for the Department. Its responsibility is to give design leadership to USDA's information programs through print, exhibits, and other media. The guiding principle of this WCF operation is to provide appropriate visual communication materials for specifically targeted audiences, clear message-related images at reasonable costs. The Center has a full complement of state-of-the-art electronic work stations, applications, sign-maker, scanners, and printers.

The graphic design staff handles over 3,500 visual requests a year including: brochures, manuals, publications, books, periodicals, presentation materials, posters, symbols and specialty items.

The exhibit area includes planning, interpretation, design, fabrication, shipping, installation, and warehousing. We provide contracting advice, written specifications, model building, budgeting, audience analysis, site surveys, and blueprints and offer a wide range of expertise. Projects include table top displays, trade shows, traveling exhibits, large scale permanent displays in visitor centers, outdoor interpretive signage, special events, and interiors of buildings.

A number of permanent major visitor centers for FS, FCIC Crop Insurance Marketing directives, reaction for the flood disaster, nutrition material, food stamps and numerous agency programs. We produced visual materials for national, international, regional and local USDA offices.

Printing -- During the summer of fiscal year 1993, OC encouraged USDA agencies to use creativity in providing information to customers while reducing printing cost (e.g., electronic formats, cost sharing with other agencies, less expensive printing materials, production of fewer, but targeted publications, etc.).

The following is a list of the publications and the number printed in OC during Fiscal Year 1992 and 1993:

	<u>FY 1992</u>	<u>FY 1993</u>
Printing through main GPO or on contract	7,380	6,387
Miscellaneous orders through GPO's Rapid Response Center (RRC), GPO's Regional Printing Procurement Offices (RPO), Federal Prison Industries (UNICOR), and Commerce	1,699	1,193
Composition (In-House USDA)	996	1,000
Printing through USDA Duplicating Facility (OO):		
Miscellaneous orders placed through USDA Facility	143	75
Miscellaneous orders reviewed and cleared for printing in USDA Facility	1,059	598
Waivers for jobs not presented to OPA for clearance	<u>4,295</u>	<u>4,512</u>
Total Printing Orders	<u>15,572</u>	<u>13,765</u>

COORDINATION AND OVERSIGHT

The Coordination and Oversight Center includes the communication coordinators team and the review team functions. OC's review team separates the creative work of OC from the oversight work, while reviewing, and overseeing the news and information products of the agencies for editorial content, design, and video production.

During fiscal year 1993, OC established at the Under/Assistant Secretary levels seven (7) Communication Coordinator positions. These individuals provided information support and coordination functions, vertically and horizontally with all other USDA information support levels. Communication Coordinator positions were advertised Department-wide and filled by career employees on a competitive basis.

The review staff is working with the American Association for the Advancement of Science and the National Agricultural Library to publish a book in English entitled "Five Continents" by the late Dr. Nikolay Vavilov, one of the world's leading botanists and a friend of the former Secretary of Agriculture, Henry A. Wallace. Vavilov worked closely with USDA plant geneticists and breeders in the 1920's and 30's and identified eight specific areas around the world where he believed farmers first domesticated plants.

The review team is working with the Soil Conservation Service and the Russian Academy of Agricultural Sciences, to publish a joint United States/Russian publication on soil and water conservation. The final product will be a four-color, high-quality, bilingual publication of use to both nations. There will be 10 articles from each side, with multiple authors. The working title of the book will be "Protection of Soil and Water Resources".

ADMINISTRATION

OC serves as USDA's central coordinating unit for the Freedom of Information Act (FOIA) and its amendments (Privacy Act and Commuter Matching and Privacy Protection Act). Department regulations and guidelines are updated to conform with amendments to the law or new directives from the Department of Justice and

Office of Management and Budget. A Data Integrity Board, required by the Computer Matching Act of 1988 was established and is presently chaired by the Director of OC.

Information Dissemination and Distribution -- OC was the first Federal agency to use a fax-on-demand system to allow reporters, using voice prompts on a telephone, to request and receive on their fax machine news releases, features, and backgrounders on specific subjects. Our AgNewsFax system allows a user to call 24-hours a day, 7 days a week to receive faxed releases. These releases are listed by number, subject or date, and some are in Spanish. Presently, the fax-on-demand system is being updated to use state-of-art technology in dissemination of information. Electronic dissemination is currently limited to the use of the AgNewsFax system and two electronic mail systems (i.e., WordPerfect Office and FTS2000). OC is in the process of upgrading the AgNewsFax system to expand the volume of information disseminated, thereby improving service to its customer base users. However, improving service to existing customers goes beyond simply making information available. Different USDA customers have different needs and making the system responsive to those different needs is a means of improving service. OC will be using the system's capability of broadcasting information selectively to targeted regions and media.

Computerized Information Delivery Service -- During fiscal year 1993, OC continued to offer its computerized information delivery service (CIDS) as an alternate means of accessing USDA information. This information includes national and regional press releases, economic and statistical reports, market reports, export trade leads, agricultural research briefs, and other information released by USDA.

Farmer Information Survey -- OC commissioned from the National Agricultural Statistics Service (NASS) a survey of American farmers to determine where they get their information about USDA programs and other kinds of information important to their work. Respondents were asked to identify their sources of farm information, USDA programs, computer usage, use of a toll free number to obtain information, and to indicate if they received USDA publications, etc. This survey determined that: "Across the U.S., about one-fourth of the farm operators reported owning a computer" and "32 percent of the respondents indicated they would use a USDA computer bulletin board." "This is higher than the percent of farm operators who own a computer because an operator could use a computer at a County Extension office or another location (i.e., public library) to access the bulletin board."

USDA Bulletin Board System (USDA/BBS) -- Fiscal year 93 was also spent in determining that a significant opportunity for enhancing information dissemination and broadening our customers access to information could be enhanced through the use of a USDA Bulletin Board System (BBS). We are in the process of preparing both the functional and technical design of this system. A bulletin board system will allow the public to access information as well as download files to their local computers.

Distribution -- Publishing Distribution handled 9,037 telephone calls for information/publications from members of the Congress for fiscal year 1993.

Regulation Review -- OC has been in the process of reviewing and updating appropriate sections of Departmental regulations to reflect the new OC, incorporating a "customer service orientation," and to reduce regulations to the minimum required.

Publications Audit -- OC conducted a comprehensive communications audit of (external) publications as a baseline for reviewing unproductive communication expenditures, and improving the effectiveness of communication products planned for the future.

Annual Report and the 1993 Yearbook of Agriculture -- The 1993 Secretary's Annual Report Part 1, issued late in the calendar year, summarized the Department's activities for the past year. The decision was made not to publish Part 2, the 1993 Yearbook of Agriculture, entitled "Nutrition: Eating for Good Health."

PUBLIC LIAISON (PL)

Public Liaison (PL) develops and maintains liaison with farm, trade, consumer associations, national resource and environmental groups and with organizations representing women, minorities, and educational groups. PL also plans and coordinates policy and educational briefings in Washington, D.C. and across the country. PL participates in national meetings, conferences, and programs to provide and disseminate information about USDA and its programs. In working with a diverse range of constituents, agriculture and interest groups, PL acts as a clearinghouse to keep USDA agencies apprised of issues and concerns voiced by outside groups, many of whom have never before participated in USDA programs.

World Food Day -- PL facilitated a diverse range of World Food Day activities by serving as lead coordinator for Federal Agencies. USDA developed and distributed 2,000 calendar brochures promoting World Food Day events sponsored by the U.S. Departments of Education and Housing and Urban Development, the U.S. National Committee for World Food Day, the United Nations' Food and Agriculture Organization, the World Food Prize, and the U.S. Information Agency. The brochure also promoted "The President's Report to the U.S. Congress on World Food Day," prepared by USDA in collaboration with the Agency for International Development.

PL also sponsored a "Biodiversity Teleconference" as part of a satellite conference broadcast to colleges and other sites throughout the Western Hemisphere and provided a package of radio and television programming via satellite and tape to stations across the country.

Visitors Center -- The Center handled 55,356 telephone calls for information and assisted 4,341 visitors. Because of the Visitors Center's frequent interaction with the public, they also act as a clearinghouse for the most commonly requested USDA publications available.

National Service -- PL coordinates and leads USDA's efforts in National Service initiatives. PL has formed a task force of USDA working groups to study and orchestrate the agency's participation in specific National Service programs focusing on rural development, anti-hunger, empowerment and environmental efforts.

Van Ness Tutoring Program -- Van Ness Elementary School in Southeast Washington is USDA's Partnership School. The core of PL's assistance to the Partnership School participation involves recruiting and coordinating USDA employees who work two (2) hours a week with students at Van Ness. Last year, 60 USDA employees provided tutoring assistance. PL also coordinates a number of other volunteer activities to benefit Van Ness students, including mentoring, obtaining software and computers for school use, and sponsoring clothing and toy collection drives for students.

Midwest Flood Support -- PL coordinated a variety of information in response to the needs of rural Midwest flood victims. A packet detailing specific assistance available from USDA programs was distributed to the nine flood-affected states via volunteer organizations, state and local offices, state departments of agriculture and governor's offices. Fact sheets were also made available through fax-on-demand.

Public Liaison staff also worked with the Federal Emergency Management Agency (FEMA) to publish five issues of a joint USDA-FEMA newsletter which detailed interagency governmental and volunteer assistance available for flood victims.

Seven hundred thousand copies of the RECOVERY TIMES were distributed to flood victims in the nine states of Iowa, Illinois, Missouri, Nebraska, Kansas, South Dakota, North Dakota, Wisconsin and Minnesota through the Agricultural Stabilization and Conservation Service, Farmers Home Administration, Soil Conservation Service, and the Extension Service.

Public Liaison Council -- PL has formed a Public Liaison Council to share information on outreach, and requests for briefings and suggested speaking engagements in Washington and throughout the country for Assistant and Under Secretaries. The Council meets periodically to discuss ways to improve and coordinate outreach to constituent groups.

ARS-HNIS ACTIVITIES

INCREASE COVERAGE OF INFANTS AND CHILDREN

Mr. DURBIN. The budget request includes an increase of \$7,562,000 to conduct a special survey of children's food intakes in response to a 1993 National Academy of Sciences Report on Pesticide Residues in the Diets of Children. This study concluded that food consumption patterns for infants and children differ markedly from those of adults, and that the current regulatory system does not specifically consider infants and children. Are children currently included as part of the data gathered for the Continuing Survey of Food Intakes by Individuals—CSFII?

Response. Yes, the CSFII collects intake data from infants and children. Compared with the earlier surveys, the CSFII 1994–96 includes a larger sample in selected age-sex groups, specifically young children and elderly.

Mr. DURBIN. Will this requested increase be used to expand the CSFII or administer a separate survey specifically designed to collect information on infants and children?

Response. The requested increase will be used to conduct a separate survey of infants and children only. The survey will use methodologies similar to those used in CSFII 1994–96 and will be conducted concurrent to CSFII 1996, in order that the data from this special survey can be combined with intake data on infants and children from CSFII 1994–96. The purpose of the special survey is to provide EPA with additional intake data on infants and children to improve its short term abilities for pesticide exposure assessment.

Mr. DURBIN. How long will it take to design this survey? Will it be done in-house or contracted out?

Response. This survey will be designed in-house with input from an interagency food safety working group with representation from USDA, EPA, FDA, DHHS, and the Bureau of the Census. Outside experts will also be used in designing the survey. The collaborative design work will continue through December 1994. Data collection for the survey will be contracted out.

Mr. DURBIN. Please provide a detailed breakout of how the \$7,562,000 will be used?

Response. The proposed use of the \$7,562,000 will be used as follows:

\$5,000,000 is requested for the design and execution of a separate survey of infants and children which will supplement the CSFII 1994–96. Two days of intake data will be collected for approximately 4350 infants and children. Data collection costs are expected to increase because of the additional screening costs associated with locating appropriate infants and children for participation in the survey, and because of the need to interview multiple caregivers to capture a complete day of intake.

\$1,000,000 is requested for statistical research to link intake data from the CSFII 1989–91 and NHANES III: Phase I (1988–91). The results from this research will be used to provide EPA with additional intake data for infants and children from existing surveys during the contract period for the infants and children survey.

\$1,562,000 is requested for an automated dietary interview to be developed jointly by USDA and DHHS that will not only address EPA's data needs long-term, but also the public's need for continuing and comparable intake data from the CSFII and NHANES. The National Nutrition Monitoring and Related Research Act mandates the preparation of a 10-year comprehensive plan for nutrition monitoring and related research. The goal of the plan is to establish a comprehensive nutrition monitoring and related research program by collecting quality data that are continuous, coordinated, timely, and reliable and by using comparable methods for data collection and reporting of results. EPA has stated, in the development of strategies to meet its long-term needs in the area of food consumption, it fully supports efforts to improve the comparability and coordination between the CSFII and NHANES in its long-term strategies.

CSFII AND NHANES SURVEYS

Mr. DURBIN. The justifications state that as part of this effort, the CSFII database will be merged, if possible, with the National Health and Nutrition Education Survey, NHANES, data base to address the short term data needs of the Environmental Protection Agency, EPA. What are EPA's short term needs?

Response. The Environmental Protection Agency—EPA—is currently using data from USDA's Nationwide Food Consumption Survey 1977–78 as the food consumption data base for its pesticide exposure assessments. In the interim, before the data from the proposed new special infants and children survey are available in 1997, EPA has a need for more current data that reflect changes in national demographics

and dietary patterns. To provide EPA with more timely data from current sources, it is proposed to extract and integrate food consumption data from the CSFII 1989-91 and NHANES III: Phase I (1988-91).

Mr. DURBIN. What information is collected as part of the NHANES survey? How is this information different from the information gathered as part of the CSFII survey?

Response. Both surveys collect a similar core of dietary intake information. However, NHANES data is correlated with health status, while CSFII data is correlated with socio-economic factors important to diet and health. The NHANES survey collects one day of dietary intake data in selected regions during each season (northern regions during the summer and southern regions during the winter) of the year. Two days of dietary intake information are collected by the CSFII, as well as information on food expenditures, sources of foods, and attitudes and knowledge about diet and health. The CSFII data are collected nationwide during all seasons.

Mr. DURBIN. Is there a fiscal year 1995 budget request to increase the NHANES survey to include more infants and children?

Response. To our knowledge, there is no FY 1995 budget request by DHHS to increase the NHANES survey to include more infants and children. The interagency food safety working group which developed the proposals for both the supplemental survey and linking of the CSFII and NHANES data included a representative from the National Center for Health Statistics, DHHS, which sponsors the NHANES survey. It was agreed by this working group that a survey to supplement the CSFII 1994-96 would be the most cost-effective and timely way to provide EPA with intake data on infants and children while planning progresses for future CSFII and NHANES. Data collection for NHANES III is scheduled to be completed in 1994.

EPA'S PREFERRED SAMPLE DISTRIBUTION

Mr. DURBIN. The development of a special survey of children's food intakes will be based on EPA's preferred sample distribution. What is this preferred sample distribution?

Response. In July, 1993, EPA provided the Agency with "judgment" numbers of infants and children. EPA has stated that these numbers, when added to the numbers of infants and children to be provided by the CSFII 1994-96, would substantially improve EPA's interim abilities until long-term strategies can be realized.

EPA FUNDING

Mr. DURBIN. Will you receive any funding from EPA for this additional work?

Response. No. EPA has stated that it cannot provide funds for these proposals due to budget constraints, although it fully supports the Agency's budget requests.

Mr. DURBIN. What is meant by the statement in the notes that the survey will entail contracts to work in even greater cooperation with EPA, FDA, and other health and scientific community to implement recommendations contained in the Academy's report?

Response. In response to recommendations in the 1993 National Academy of Sciences Report on Pesticides in the Diets of Infants and Children, two proposals were developed by an interagency food safety working group made up of representatives from USDA, EPA, FDA, DHHS, and the Bureau of the Census. Both proposals, the new infants and children survey and the linking of data from CSFII 1989-91 and NHANES III, would be implemented through a competitive bid process. Representatives from the food safety working group will continue to collaborate on the development of the contracts for the initiatives.

NATIONAL NUTRIENT DATABANK SYSTEM

Mr. DURBIN. The requested increase of \$200,000 for the National Nutrient Databank System will be used for quality improvements of data management. Please provide some examples of how you plan to do this.

Response. The National Nutrient Data Bank—NNDB—is used to collect and summarize data on the composition of foods in the American food supply.

The current system was designed over ten years ago. Since that time, the following changes and advances have occurred to make the system obsolete: (1) tremendous advances have been made in computer technology in both hardware and software, especially data base management software; (2) the numbers and types of foods to be covered by the data bank system have increased several times over; (3) several procedures used by the staff that have been developed in the last few years, cannot be performed by the hardware and software currently in use for the NNDB. The new system will utilize advanced off-the-shelf data management software, thus

eliminating the need to maintain proprietary, custom-written programs which are difficult to maintain, modify, and enhance. Emphasis will be placed on receipt of data in electronic form to reduce time and errors associated with data entry. Procedures developed since the last system was designed and which provide new support externally to the system will be automated to increase operating efficiency and decrease errors associated with manual processes.

Mr. DURBIN. How will this new system differ from the current system?

Response. The new system will be designed to take advantage of new data base management technology and will replace proprietary, custom-written computer programs which are not easily modified or expanded. The system will be maintained on agency computer hardware, instead of an off-site mainframe computer. The new system will utilize advanced user-interface techniques, such as on-line data coding and editing, to eliminate current manual procedures. More flexible, off-the-shelf software will be employed. This will enable modifications and additions as needed without necessitating a system revision. The new system will also be designed to include additional information about data quality, something that researchers have indicated is important for their use of the data in scientific research. Also, since the last system was developed, international exchange of food data has become increasingly important; therefore, international standards that have been adopted for food composition data by the International Network of Food Data Systems—INFOODS—will be accommodated to facilitate international exchange of data. These system enhancements should increase the efficiency with which the Agency can accomplish its mission to provide information about the nutritional content of the U.S. food supply and should also increase the utility of the information that is produced.

Mr. DURBIN. Do you maintain this databank system within USDA or is it maintained in the private sector through a contract?

Response. The Agency maintains the databank system within USDA.

FNS REIMBURSEMENT

Mr. DURBIN. What services were performed for the Food and Nutrition Service that resulted in a reimbursement of \$715,390 in fiscal year 1994?

Response. There are three separate items that account for this reimbursement. First, \$400,000 was transferred from the Food and Nutrition Service for development of the Nutrient Data Base for Child Nutrition Programs. This is the data base that will be used for the School Lunch Program's Nutrient Standard Menu Planning Demonstration Project which begins with the 1994-95 school year. Development of this data base requires extensive work within the Nutrition Monitoring Division.

This work is divided into two distinct components. The first component involves the design and development of a set of interrelated data bases containing the various elements required for developing school lunch menus to meet a nutrient standard. Examples of these elements are values for 14 food components for each food item; data on weights of various measures and portion sizes for each food; brand names and Child Nutrition Label Information associated with different foods; quantity food school lunch recipes; buying guide data; etc. The second component involves developing a procedure to obtain and evaluate data from food companies about foods that are targeted for the School Lunch program. Because of the importance of the School Lunch program and the need for the data base to contain nutrient data of the highest quality, special attention has been paid to ensuring that data pass a critical evaluation before they are accepted. An electronic form for data submission by food companies has been developed, and a computer program to facilitate review and evaluation of the data has been developed and is currently being tested.

A prototype of the Nutrient Data Base for Child Nutrition Programs was made available through the Nutrient Data Bank Electronic Bulletin Board in January 1994. The data base will be updated periodically with data received from companies.

Second, \$12,000 was transferred for reimbursement for an employee detail.

Third, \$303,390 was transferred for the review and evaluation of the Thrifty Food Plan. The study had not started when the Human Nutrition Information Service was transferred to the Agricultural Research Service on February 20, 1994. These funds were returned to the Food and Nutrition Service in March 1994 at their request.

PERSONNEL COMPENSATION AND BENEFITS

Mr. DURBIN. You are proposing staff year reductions in fiscal year 1995, yet your total personnel compensation and benefits funding is projected to increase by almost \$300,000. Would you tell us the reason for this.

Response. The President's FY 1995 budget estimated FY 1994 personnel costs of \$5,191,000 and projected FY 1995 costs of \$5,371,000, a difference of \$180,000. Even

though the former HNIS is scheduled to lose three FTEs, personnel compensation increased by a projected 2 percent pay raise as directed by the FY 1995 Program and Budget Proposal plus an increase in benefits of \$82,000.

COST OF CSFII SURVEY

Mr. DURBIN. What is the total cost of the fixed price contract for the 1994 through 1996 Continuing Survey of Food Intakes by Individuals and the Diet and Health Knowledge Survey?

Response. The total cost of the fixed price contract for the 1994-1996 Continuing Survey of Food Intakes by Individuals—CSFII—and the Diet and Health Knowledge Survey is \$13.5 million. This covers the cost of 1½ years of survey development, including a pilot study of all survey operations conducted nationwide in ten sites. Survey development also covers the development of automated systems to track every step of the data collection and processing. This system provides information essential in monitoring response rates, maintaining quality control, and speeding the release of data. The total cost also covers collection of intake data from 15,000 individuals over three years nationwide and costs for processing the data. The Agency has been very aggressive in implementing strong management and quality control procedures, both as part of the CSFII 1994-96 contract and its in-house operations to assure that the survey provides accurate data in a timely manner. The pilot study demonstrated that the procedures established for this survey were successful. The Agency also established requirements with penalties for ensuring specified response rates as part of the contract.

Mr. DURBIN. What is the cost per participant?

Response. The cost per participant for both the CSFII and the DHKS is approximately \$800. This excludes the cost of survey development (\$1.1M) a procedure recommended by the Bureau of the Census staff. The CSFII collects two separate days of intake data; it is the only survey to collect multiple days of data for all age groups. Multiple days are needed to determine the proportion of individuals who are at nutritional risk in a population and for addressing food safety concerns. The follow-up DHKS survey is the only national survey that provides information on dietary attitudes and knowledge, which can be combined with food and nutrient intake from the same individuals interviewed in the CSFII. This information is essential for developing effective programs to improve American diets. The Independent Government Cost Estimate (IGCE) for the CSFII 1994-96 was developed with collaboration with the Bureau of the Census. Bureau of the Census staff advised that the CSFII costs are in line with the costs of surveys of similar complexity and size.

CSFII/DHKS DATA TAPES

Mr. DURBIN. The Explanatory Notes state that data tapes providing the results from the 1989 and 1990 CSFII/DHKS have been made available. What were the results from these surveys?

Response. Data tapes from all three years of data collection (1989, 1990, and 1991) are available. Some major findings from both the CSFII and the DHKS will be provided for the record.

[The information follows:]

There was a shift to a lower-fat, higher carbohydrate diet between 1977-78 and 1989-91. During this period, the percentage of calories from fat dropped from 40 percent to 34 percent. However, the amount of fat in the average diet is still higher than the 30 percent of calories recommended by the Dietary Guidelines for Americans. Only about 23 percent of Americans 20 years and over have diets that are at or below the recommended level.

More than 75 percent of main meal planners/preparers were aware of health problems related to the consumption of fat, yet the diets of most did not meet the dietary recommendations for fat. Heart disease was the disease most frequently cited as related to fat intake—by 63 percent of both men and women. About 86 percent of meal planners were aware of health problems related to cholesterol and more than half of men and three quarters of women met the recommendation to consume less than 300 milligrams of cholesterol daily.

Children and teens are consuming more ready-to-eat cereals, grain mixtures such as pizza, and lowfat and skim milk and less vegetables, yeast breads, beef, and eggs than they did in 1977-78. School age children are drinking more noncitrus juices and teens are drinking more soft drinks.

Of particular concern is the low consumption of fruit among children and teens. Almost 60 percent of teens and 35 percent of elementary school children had no fruit

or fruit juice on the first day of the survey. The Food Guide Pyramid suggests that individuals consume two to four servings of fruit daily.

In general, nutrient intakes by Americans exceed the Recommended Dietary Allowances (RDA) for protein, vitamin A, vitamin C, thiamin, riboflavin, niacin, folate, vitamin B-12, and phosphorous. For some nutrients—vitamin E, vitamin B-6, calcium, magnesium, iron, and zinc—intakes were below the RDA for many sex-age groups.

Results from the surveys have been presented at the 1993 American Public Health Association annual meeting, published in Agriculture Information Bulletin 685, and used by The Assistant Secretary for Food and Consumer Services in public hearings on the School Lunch Program.

USER FEES

Mr. DURBIN. Information from the National Data Bank and the Agriculture Handbook 8 are available through hard copy or electronically. Do users pay a fee to receive this information?

Response. Users must pay for Agriculture Handbook No. 8, which is sold by the Government Printing Office. The data are available electronically from our Nutrient Data Bank Electronic Bulletin Board without cost to the user, except for the cost of the phone call. The data are also available electronically through the Internet without cost to the users. Electronic forms of the Data Bank are also sold by the National Technical Information Service.

NUTRIENT DATA BASE FOR CNP

Mr. DURBIN. What is the status of the Nutrient Data Base For Child Nutrition Programs? Would you describe this initiative in further detail for the record.

Response. The National Nutrient Data Base For Child Nutrition Programs is being developed cooperatively by the Food and Nutrition Service and ARS. This data base will be used in a National School Lunch demonstration project of Nutrient Standard Menu Planning beginning with the 1994-95 school year. Sources of data are the USDA Nutrient Data Base for Standard Reference, USDA values for commodity foods, calculations of the nutrient content of food school lunch recipes prepared in quantity, and data submitted by the food industry for foods targeted for use in the School Lunch program. Nutrients included in the data base are:

Protein	Calcium
Total	Iron
Saturated Fat	Sodium
Cholesterol	Vitamin A (IU)
Food Energy	Vitamin A (RE)
Moisture	Vitamin C
Total Dietary Fiber	Ash

Because of the importance of the School Lunch program and the fact that the data base will be used to make important decisions related to school lunch menu planning, it is imperative that data used in this demonstration project be of highest possible quality. Food companies producing foods targeted for the School Lunch program have been asked to submit data for their products. An electronic form for submission of data by food companies has been developed and is sent to companies upon request. Information related to data quality is requested as part of the form. A computer program to facilitate review and evaluation of data submitted for the data base has been developed and is currently being tested.

A prototype of the data base was placed on the Nutrient Data Base Bulletin Board in January 1994. The prototype serves as a model of the final data base. It was designed to assist software developers in preparing the computer programs that will use the data base in the demonstration project scheduled to begin September 1994. The data base will include all the foods requested by the Food and Nutrition Service in time for the beginning of the demonstration project. As information is received from companies, it is evaluated and, if acceptable, placed in the data base. This process will continue throughout the demonstration project and new releases of the data base should take place approximately every six months.

FOOD GROUPING SYSTEM

Mr. DURBIN. USDA, EPA, and FDA are in the process of redefining the Food Grouping System. Has a contract been awarded?

Response. USDA, EPA, and FDA work together through the Pesticide Data Program—PDP—, which was designed to provide government agencies with an im-

proved data base to respond more effectively to food safety issues. Towards that effort we are developing and will maintain the Food Grouping System.

We have an interagency agreement with GSA to facilitate development of the automated Food Grouping System—FGS—. A procurement request issued in 1993 has been revised to clarify some of the contract requirements. Final revisions to the requirements were submitted to GSA in the beginning of April 1994. GSA plans to award the contract mid-summer, 1994. This contract for the automated system will permit more projects to benefit from data produced from this innovative methodology which integrates complex data files, and thus, provides consistency in reporting ingredient and commodity intake data for user of food consumption data.

Although the contract to automate the Food Grouping System has been delayed, development of FGS data files and programs has continued. Recently, FGS project data sets provided information on—

FGS commodities files developed for review by EPA

Consumption of servings of fruits and vegetables (collaborative project with the Division of Cancer Prevention and Control, National Cancer Institute)

Consumption of meat, poultry and seafood for estimating risks from heterocyclic amines (collaborative project with the Environmental Epidemiology Branch, NCI)

Cereal grain product consumption for assessment of health implications of proposed folacin fortification levels (collaborative project with Office of Food Labeling, FDA)

Ingredient intake from meat and grain food mixtures—such as beef stew and pizza broken down to meat, vegetables, crust or flour (in-house research)

Nutrient intake from vegetables reported separately and including vegetables consumed as ingredients in all foods (in-house research).

Projects such as those listed above demonstrate the capabilities of the FGS, both conceptually and operationally.

NUTRIENT CONTENT OF THE U.S. FOOD SUPPLY

Mr. DURBIN. Has the report entitled, Nutrient Content of the U.S. Food Supply, been published? Briefly summarize the results of this report. What was the cost of doing this report? Please provide a copy for the record.

Response. The biannual report entitled, "Nutrient Content of the U.S. Food Supply" (USDA) was last published in 1992 (Home Economics Research Report No. 50). An update to this report has been completed and is scheduled to be published in 1994. The cost of printing this report in 1992 was \$3,500 for 1,000 copies.

A summary of the report is as follows:

At the beginning of the century, animal sources contributed over three-fourths of the total fat in the food supply. This dropped to about half of the total in recent years. In the past 20 years, use of red meats and eggs has declined and a shift from whole to low-fat milk has occurred. Fats from vegetable sources have concomitantly increased. The overall use of fruits and vegetables has increased during this time with the expanded use of non-citrus fruits and some fresh vegetables—lettuce, onions, tomatoes, carrots, cauliflower, and broccoli accounting for this increase. A study of omega-3 fatty acids in the food supply showed that the use of fish, a main source of omega-3 fatty acids, increased from 12 pounds per capita in 1935–1939 to 19 pounds in 1985. In the late 1980's calcium levels per capita per day were almost 900 mg. These levels are higher than at the beginning of the century (740 mg. in 1909), but not as high as in the late 1940's, a peak period for both calcium and dairy products in the food supply.

USDA FAMILY FOOD PLANS

Mr. DURBIN. The cost of four USDA family food plans are released monthly. Is it necessary to release this information on a monthly basis? Who uses this information on a monthly basis and for what purpose?

Response. The USDA food plans are buying guides for nutritious diets at four cost levels—thrifty, low-cost, moderate-cost, and liberal. These plans show quantities of different types of foods to buy to prepare nutritious meals and snacks for a week. The least costly of plans—the Thrifty Food Plan—is the basis of the Food Stamp Program allotments. The cost of the current Thrifty Food Plan is based on the inflation adjusted cost of the Thrifty Food Plan's predecessor, the Economy Food Plan. The Economy Food Plan was developed using 1955 Household Food Consumption Survey data and the current Thrifty Food Plan was developed using 1977–78 survey data. An inflation adjustment is made monthly to the cost of the food plans using Bureau of Labor Statistics data.

The monthly update of the food plan costs is considered necessary and desirable by the users who include:

The USDA Food and Nutrition Service uses the cost of the food plans to set food stamp allotments. The June cost is used to determine the food stamp allotments, but monthly costs are used for forecasting and budgeting.

Public and private assistance agencies use the food plan costs to establish food allowances for needy families, to determine payment rates for care in foster homes, and to develop market baskets for estimating food costs.

The Internal Revenue Service, courts, and lawyers use the costs of the food plans to set rates for the care of dependents.

State institutions and camps use the costs of the food plans to estimate food needs and monitor food use.

Cooperative Extension Service, nutritionists, credit counseling services, social service professionals, and food editors use the costs of the food plans to provide guidance in planning nutritious diets for households and to convey food budgeting advice.

Mr. DURBIN. Please provide a copy of the report that was done on the Thrifty Food Plan Development.

Response. The Administrative Report CND (Adm.) 365, The Thrifty Food Plan describes the development of the Thrifty Food Plan revised in 1983. A copy of the report is retained in Committee files.

DIETARY GUIDELINES BULLETINS

Mr. DURBIN. Also provide a copy of the new bulletins on the Dietary Guidelines that have been released.

Response. We will provide for the record a copy of the bulletins, "Dietary Guidelines and Your Diet," Home and Garden Bulletins 253-1 through 8, released in July 1993. The series was written and designed for consumers, particularly for those who plan, purchase, and prepare food. The 96-page set includes seven bulletins, each of which focuses on one Guideline but emphasizes all seven Guidelines in selecting a healthful diet. Also included in the set is an "overview" bulletin which introduces all seven Dietary Guidelines and the Food Guide Pyramid. During development, three of the bulletins were evaluated by focus groups of adults. They reacted favorably to the bulletins and found them to be informative, useful, and convenient. Ease of reproducibility was a consideration during development of the bulletins. They can be easily photocopied. The bulletins are also available for purchase as a set through the Government Printing Office, Washington, D.C. Copies of all bulletins are retained in Committee files.

SURVEY SUMMARY

Mr. DURBIN. For the record, please provide a brief description of all surveys you do including the cost of each.

Response. Two surveys currently conducted by ARS' Human Nutrition Information Service are the 1994-96 Continuing Survey of Food Intakes by Individuals (CSFII) and the follow-up Diet and Health Knowledge Survey. The total cost for these surveys is \$13.5 million. Both surveys are conducted under a single-fixed price contract. For the CSFII and DHKS 1994-96, every facet was thoroughly examined and redesigned as necessary. Importance was placed on strong management and quality control procedures, in addition to procedures for ensuring high response rates. The contract was designed to meet these needs.

The FY 1995 budget includes a request for \$5 million to conduct a separate survey of infants and children. This survey will use methodologies similar to those used in CSFII 1994-96 and will be conducted concurrent to CSFII 1996. The purpose of this survey is to provide EPA with additional intake data on infants and children for its pesticide exposure assessments.

A separate Independent Government Cost Estimate is developed for each series of surveys, based on the design of the particular survey. Costs for surveys may vary depending on the sampling design, numbers of respondents, data collection methods, level of data processing, etc.

MOU AGREEMENT WITH DHHS

Mr. DURBIN. At last year's hearing, Mr. Rust told the Committee that the MOU agreement between USDA and DHHS outlining general procedures for review of dietary guidance for the general population or identified population subgroups was in final negotiations. What is the status of this agreement? What has been decided?

Response. A MOU between USDA and DHHS on the General Procedures for Review of Dietary Guidance for the General Population or Identified Population Subgroups has been signed by Dr. Plowman, Acting Assistant Secretary for Science and Education, USDA and by Dr. Lee, Assistant Secretary for Health, DHHS. This MOU formalizes the joint review and clearance processes that have been in place for some time. Both Departments have committees composed of representatives from each of the Agencies that play a role in nutrition research and education. Departmental liaison members serve on both committees. The committees review materials from both Departments to ensure technical accuracy and consistency with Federal nutrition policy. Materials are not released without the approval of these committees.

NATIONAL NUTRITION MONITORING ADVISORY COUNCIL

Mr. DURBIN. Did the National Nutrition Monitoring Advisory Council meet in fiscal year 1993? If so, what were its findings and recommendations? Does it plan to meet in fiscal year 1994?

Response. The National Nutrition Monitoring Advisory Council did meet in May 1993. The meeting focused on identifying, data uses and needs of the States, and briefings and updates on a number of National Nutrition Monitoring Program activities. In addition, there was a panel presentation of invited speakers from 4 States who provided an overview of nutrition monitoring in their State. The Council plans to follow-up with more specific objectives in the area of State data needs and uses emphasized by the Panel. An update on the General Accounting Office (GAO) Evaluation of the Nutrition Monitoring Program was presented by a staff member. The Council expressed concern about the lack of a representative for State and local data needs on the advisory panel formed by GAO to assist in the evaluation. The Council recommended that this concern be addressed by GAO.

The Council was asked for their comments and input on a proposal for prioritizing Ten-Year Plan activities currently being discussed by the Interagency Board for Nutrition Monitoring and Related Research. The Council overall did not have major concerns with the proposal for prioritization and provided helpful suggestions for assuring that activities of a lower priority would not be slighted.

The Council provides a liaison member to the Federal Steering Committee for the Third Scientific Report on Nutrition Monitoring. This report, required by the National Nutrition Monitoring Act, is being developed under contract with the Life Sciences Research Office of the Federation of American Societies for Experimental Biology. The Council has suggested policy/technical areas to be addressed in the report to the Steering Committee. These recommendations have been sent to the contractor.

The Council also met in fiscal year 1994 in October 1993. Their next meeting is scheduled for November 27-28, 1994.

NUTRITION MONITORING TEN-YEAR PLAN

Mr. DURBIN. The Ten-Year Plan on Nutrition Monitoring Activities was transmitted to Congress in January 1993. What is the status of this Plan?

Response. Following approval by the President and transmittal to Congress of the Ten-Year Plan in January 1993, the final Plan was published in the Federal Register on June 11, 1993. The Plan includes timelines for 1992-2002 for each of approximately 70 activities that were developed jointly by Federal agency representatives, and identifies agencies and staff to implement the activities over a ten-year period. Implementation of scheduled activities began in 1992, and has continued through the present. In accordance with a requirement of the Plan that calls for annual progress reports by the responsible agencies, progress on these activities in 1992 was detailed in the "1992 Ten-Year Comprehensive Plan: Approach and Progress Document" and summarized in the 1992 Executive Summary. Over 500 copies of the "1992 Executive Summary" were distributed to users of nutrition monitoring data. The "1993 Approach and Progress Document" and "Executive Summary", which is nearing completion, will also be extensively distributed.

CONTINUING SURVEY USERS' GROUP

Mr. DURBIN. The Continuing Survey Users' Group is a group made up of representatives from a number of agencies within the Federal Government who use the information obtained from your surveys. Did this group meet in fiscal year 1993? If so, what were its findings and recommendations? Does it plan to meet in fiscal year 1994?

Response. The Continuing Survey User's Group was begun to assist in the planning and development of the Continuing Survey of Food Intakes by Individuals. This group met several times in 1992 during preparation of the contract for the CSFII 1994-96. In fiscal year 1993, members of the group were sent copies of the questionnaires to be used in the CSFII pilot study and asked to provide comments before the pilot study was implemented. Recently, members were sent copies of the questionnaires used in CSFII 1994 and asked to provide comments in preparation for the CSFII 1995 questionnaire. This group will be convened later in fiscal year 1994 to discuss preliminary results from CSFII/DHKS 1994 and to begin planning for the next CSFII series.

EXTRAMURAL CONTRACTS

Mr. DURBIN. Please provide a list of all extramural contracts, including the cost of each, that were used in fiscal year 1993 as well as those ongoing in fiscal year 1994.

Response. The list of extramural contracts for FY 1993 are as follows:

Monitoring Contents of Lipid Components of Ethnic & Geographic Specific Foods with University of Maryland, FY 1993 cost \$64,638.

Proximate, Vitamin & Mineral Contents of Specific Foods, Southern Testing & Research Lab, FY 1993 cost \$78,070.

Advisory and Assistance Services for Nutrient Data Research Branch with the University of Missouri, FY 1993 cost \$77,177.

Extramural contracts ongoing in FY 1994:

Continuing Survey of Food Intakes by Individuals and the Diet and Health Knowledge Survey with Westat, Inc. Rockville, MD. Survey collection was funded in 1994 at \$4,174,962; 1995 \$3.9 million and 1996 \$4.2 million.

Scientific Report on Nutrition Monitoring and Related Research with the Life Sciences Research Office of the Federation of American Societies for Experimental Biology. The National Nutrition Monitoring and Related Research Act of 1990 calls for DHHS and USDA to jointly contract with an independent scientific body to develop a scientific report on the dietary, nutritional, and health-related status of the people of the United States. The Act mandates an updated report every 5 years. The total cost of the report, incurred in FY 93, is \$699,948, shared by USDA (\$347,448) and DHHS (\$352,500), with USDA providing contractual and administrative oversight.

PESTICIDE DATA PROGRAM

Mr. DURBIN. Please update the table that appears on page 611 of last year's hearing record showing the amount spent on the pesticide data program to include fiscal year 1994.

Response. The funding spent in support of the Pesticide Data Program in fiscal years 1990-1994 is as follows:

Fiscal year	Budget amount	Funds obligated—FGS planning and developing	Staff years
1990		\$225,000	1.5
1991	\$500,000	500,000	5.0
1992	500,000	500,000	6.0
1993	500,000	500,000	5.0
1994	200,000	200,000	4.0

STUDY TO ASSESS NEEDS OF PREGNANT TEENS

Mr. DURBIN. What were the results of the study done in 1991 to assess the needs of pregnant teenagers?

Response. A cooperative agreement to assess the nutrition education needs of pregnant adolescents and develop prototype materials for this audience was awarded to the University of Tennessee, Knoxville, in September 1991 and was completed in May 1993. The research team at the University of Tennessee are recognized experts in the field of adolescent nutrition. The multidisciplinary team was led by Dr. Jean Skinner, Professor of Nutrition at the University of Tennessee, who is also President-Elect of the Society for Nutrition Education (an international organization for professional nutrition educators established in 1968).

The research was initiated because of interest in improving the nutrition of pregnant teenagers and the health of their infants. While there was general consensus on nutritional needs and healthful eating patterns for teens during pregnancy, little information was available about nutrition topics of most interest to the teens themselves, or ways to deliver the information that would be most appealing and useful to them. Nutrition education research over the last decade has shown that qualitative market research methods such as focus groups and indepth interviews can provide rich descriptive data on comprehension, acceptance and perceived usefulness of nutrition materials and can indicate modifications that can make the information more responsive to audience needs.

The project was conducted in three phases. In phase 1, a needs assessment was conducted by literature review and workshop discussions with nutrition and health professionals who work with pregnant teenagers. In phase 2, focus groups were conducted with a total of 92 pregnant or postpartum teens, including both blacks and whites, rural, and urban participants, who discussed their nutrition information needs and interests, and reacted to samples of available materials in print or video format.

Results indicated that teens preferred a video format with teenage actresses over print materials. Teens wanted messages related to eating for the baby's health and messages about food rather than specific nutrients. In phase 3, these results were used to develop a 10-minute prototype video with these messages; the video was shown to 116 pregnant or postpartum teens in focus groups or individual interviews. Evaluation methods allowed girls to describe their reactions in their own words.

Phase 3 results indicated they considered the video suitable for teens like themselves; this perception did not differ among girls by race, urban/rural environment, socioeconomic status, or region of the country (Minnesota vs. Tennessee). Analysis of the transcribed sessions showed that the teens could identify the intended messages, understood the content and liked the presentation style. They scored the video very positively.

The final report of the study from the University of Tennessee comprehensively summarized information from the three phases of the work. The results of the study were presented at the Society for Nutrition Education Annual Meeting in July 1993 and the International Congress of Nutrition in Australia in September 1993. It is expected that articles will be published in the professional literature. The University of Tennessee was given permission to utilize and develop the video prototype.

ALL STUDIES IN FY 1993 AND FY 1994

Mr. DURBIN. Provide a list of all studies that were done in fiscal year 1993 and those ongoing in fiscal year 1994.

Response. The Agricultural Research Service conducts research in three broad areas designed to achieve the goal of improving the health and well-being of Americans through improved nutrition. The three overarching research areas are: food consumption—what Americans buy and eat; food composition—the nutrient content of foods; and nutrition education—helping Americans making informed food choices. A list of all studies that were in fiscal year 1993 and those ongoing in fiscal year 1994 is as follows:

Studies completed in FY 1993 are as follows:

Nutrient Content of Selected Key Foods. Monitoring Lipids in Ethnic and Geographic Specific Foods.

Fatty Acid Content of Selected Foods.

Nutrient Retention in Foods Prepared by Different Cooking Methods.

Nutrient Content of Ethnic and Geographic Specific Foods.

Advisory and Assistance Services for Nutrient Data Research Branch

Total Dietary Fiber Content of Foods.

Task performance in support of the Nutrition Monitoring Division.

Summary of Development of the Research Base for the Food Guide and Pyramid Graphic, several publications completed.

The Dietary Change Research Model to Assess Discrepancy Between Recommendations and Intake.

Assessment of Nutrition Education Needs of Pregnant Teenagers.

Evaluation of HNIS's Dietary Guidelines Teaching Kit for Home Economics Teachers.

Research on Educational Materials for Implementing the Dietary Guidelines for Americans.

Research on Dietary Guidance Materials for Adults with Low Literacy Skills.

Research on Dietary Guidance Materials for Older Adults.

Research on Dietary Guidelines Teaching Kit for Health Educators.

Methodology for Use of Diet, Health, Knowledge Surveys in the Assessment of Nutrition Education Theory.

Dietary Patterns: Implications for Nutrition Education.

Research on the Use of the Food Label.

Television Viewing, Activity Level and Weight Status.

Food Safety Concerns/Nutrition Concerns.

Assessment of Total Vegetable Intake Including Vegetables Consumed as Part of Mixtures.

Economic and Sociodemographic Correlates of Food Consumption.

Research on the Food Situation of Single Adults.

Iron Deficiency Prevention, Detection and Management.

Project to Evaluate Congregate and Home Delivered Meals.

Implications of Changes in the U.S. Food Supply for Nutrition Education.

Studies ongoing in FY 1994 are as follows:

Nutrient Content of Ethnic and Geographic Specific Foods Option Year 1.

Monitoring Lipids in Ethnic and Geographic Specific Foods Option Year 1.

Total Dietary Fiber and Sugar Content of Foods.

Develop Data Handling System for the National Nutrient Database for Child Nutrition programs.

Improving food intake surveys.

Continuing Survey of Food Intakes by Individuals and the Diet and Health Knowledge Survey.

Statistical and Methodological Research Related to Analysis of Food Consumption Surveys.

Improving Children's Dietary Intake Reporting.

An Analysis of Variations in Food Consumption Across Household Types and Over Time.

Relationship of Nutritional Knowledge and Attitudes to Dietary Behavior.

Publication of Summary of Nutrition Education Research Theory and Methodology.

Food Guide Pyramid Users Database.

Development of a Professional Guide on Using the Food Label as an Educational Tool.

Development of Nutrition Label Educational Materials for Consumers on Using the New Food Label in Following the Food Guide Pyramid.

Research on Educational Materials Useful in Weight Control.

Research on USDA's Dietary Analysis Program.

Nutrition Education Impact Indicator Project with the Cooperative Extension Service.

Nutrient Content of the U.S. Food Supply.

Food Supply Methodology Changes and Improvements.

Research to Develop and Maintain USDA Food Plans at Different Cost Levels.

Research on the Food Situation of Single-Mother Families.

Research to Develop Principles of Food Preparation Consistent with Dietary Recommendations.

Professional's Guide to Using the Pyramid in Menu Planning.

Guidelines for Using the Pyramid for Young Children (2-6 years).

Updating of the Research Methodology for the Food Guide.

Healthy Eating Index and Indicators of Compliance with the Food Guide Pyramid.

HUMAN NUTRITION INFORMATION SERVICE

PURPOSE STATEMENT

The Human Nutrition Information Service (HNIS) was established by the Secretary on October 1, 1981. The functions of this agency were formerly carried out within the Agricultural Research Service.

The Department of Agriculture promotes the health and well-being of Americans through improved nutrition. The Human Nutrition Information Service contributes to this mission through the conduct of national food consumption surveys, food composition research, and nutrition education programs. The Agency plays a primary role in the National Nutrition Monitoring and Related Research Program and in the development and promotion of the Dietary Guidelines for Americans.

HNIS serves the American public by conducting applied research in food and nutrition--what foods we consume and what nutrients are in those foods and how to make informed food choices.

The research and information produced by HNIS provides scientists, educators, policymakers, regulators, and health care professionals with the information needed to formulate strategies for:

- food assistance and nutrition intervention programs;
- national nutrition monitoring;
- food safety;
- development of nutrition information and education programs;
- research in nutrition and health; and
- food formulation, production, and marketing.

The Agency is located at Hyattsville, Maryland. As of September 30, 1993, there were 101 full-time permanent and 14 part-time permanent employees. A portion of the Agency's work is done via competitive contracts. These contracts are used for work that requires extensive human resources located throughout the country such as providing interviewers for nationwide surveys, or that requires specific technical expertise and equipment such as laboratory analyses of the nutrient composition of specific foods. Much of this work requires specialized technical skills that would be impractical for the agency to retain among its employees on a year-round basis.

HUMAN NUTRITION INFORMATION SERVICE

Available Funds and Staff-Years

1993 Actual and Estimated, 1994 and 1995

Item	1993		1994		1995	
	Actual		Estimated		Estimated	
	Amount	Staff-Years	Amount	Staff-Years	Amount	Staff-Years
Salaries and Expenses	\$8,538,000	109	\$11,068,000	103	\$18,403,000	100
Obligations under						
other USDA						
appropriations:						
Agricultural						
Marketing Service			56,091			
Food and Nutrition						
Service	108,000		715,390			
Nutrition Monitoring:						
Advisory Council	19,900				---	
Total, Other USDA						
Appropriations	127,900		771,481		---	
Total, Agriculture						
Appropriations	8,524,256		11,839,481		18,403,000	
Other Federal Funds:						
Department of Health:						
and Human Services	397,500		75,000		75,000	
Food and Drug						
Administration	30,000					
Total, Other Federal:						
Funds	427,500		75,000		75,000	
Total, Human Nutrition:						
Information Service	9,093,400	109	\$11,914,481	103	18,478,000	

HUMAN NUTRITION INFORMATION SERVICE

Permanent Positions by Grade and Staff-Year Summary

1993 and Estimated 1994 and 1995

Grade	1993 Headquarters	1994 Headquarters	1995 Headquarters
SES 1	1	1	1
SES 2	1	1	1
GS/GM-15	3	2	2
GS/GM-14	7	7	7
GS/GM-13	25	25	20
GS-12	19	19	19
GS-11	26	27	27
GS-10	1	1	1
GS-9	12	12	12
GS-7	8	8	8
GS-6	2	2	2
GS-5	9	9	9
GS-4	1	1	1
GS-3	0	0	0
Total Permanent Positions.....	115	115	110
Unfilled Positions end-of year.....	-13	-12	-10
Total, Permanent Employment, end-of-year.....	102	103	100
Staff-Year Ceiling	109	103	100

HUMAN NUTRITION INFORMATION SERVICE

CLASSIFICATION BY OBJECTS

1993 and Estimated 1994 and 1995

	1993	1994	1995
	----	----	----
Personnel Compensation:			
Headquarters:			
11 Total personnel compensation.....	\$ 4,555,474	\$ 4,210,000	\$ 4,308,000
12 Personnel benefits.....	899,954	981,000	1,063,000
13 Benefits for former personnel.....	---	---	---
	-----	-----	-----
- Total pers. comp. & benefits	5,455,428	5,191,000	5,371,000
Other Objects:			
21 Travel.....	56,374	40,000	45,000
22 Transportation of things.....	4,996	9,000	10,000
23.2 Rental payments to others.....	---	---	---
23.3 Communications, utilities, and misc. charges.....	192,139	80,000	100,000
24 Printing and reproduction.....	122,671	170,000	110,000
25.1 Consulting services	1,854,621	4,700,000	11,960,000
25.5 Research and development contracts.....	447,192	723,000	652,000
26 Supplies and materials..	152,176	75,000	75,000
31 Equipment.....	111,756	80,000	80,000
	-----	-----	-----
Total other objects.....	2,941,925	5,877,000	13,032,000
	-----	-----	-----
Total direct obligations.....	8,397,353	11,068,000	18,403,000
	-----	-----	-----
Position Data:			

Average Salary, ES positions.....	\$92,900	\$96,830	\$96,830
Average Salary, GM/GS positions..	\$40,194	\$39,766	\$40,561
Average Grade, GM/GS positions...	10.62	10.19	10.19

HUMAN NUTRITION INFORMATION SERVICE

The estimates include appropriation language for this item as follows (new language underscored; deleted matter enclosed in brackets):

Salaries and Expenses:

For necessary expenses to enable the Nutrition Research and Education Service to perform applied research and demonstrations relating to human nutrition and consumer use and economics of food utilization, and nutrition monitoring, \$18,403,000: Provided, That this appropriation shall be available for employment pursuant to the second sentence of section 706(a) of the Organic Act of 1944 (7 U.S.C. 2225).

This change would recognize the Nutrition Research and Education Service as a separate agency pursuant to the Secretary's Memorandum 1020-39 dated September 30, 1993.

HUMAN NUTRITION INFORMATION SERVICE

Appropriations Act, 1994.....	\$	0
Budget Estimate, 1995.....		<u>18,403,000</u>
Increase in Appropriation.....		<u>+18,403,000</u>

Adjustments in 1994:

Appropriations Act, 1994.....	\$	0
Activities transferred from Agricultural Research Service ^{a/}	<u>+11,068,000</u>	
Adjusted base for 1994.....		11,068,000
Budget Estimate, Current Law, 1995.....		<u>18,403,000</u>
Increase over adjusted 1994.....		<u>+7,335,000</u>

^{a/} Pursuant to Secretary's Memorandum No. 1020-39, on September 30, 1993, the functions of the Human Nutrition Information Service were transferred to this account from the Agricultural Research Service. Actual transfer of funds of \$11,068,000 were made in 1994. The full annual cost of these activities is \$11,068,000 for 1994 and \$18,403,000 for 1995.

SUMMARY OF INCREASES AND DECREASES

(On basis of appropriation)

Item of Change	1994 Estimated	Pay Cost	Other Changes	1995 Estimated
Human Nutrition Information Service	\$11,068,000	+\$62,000	\$7,273,000	\$18,403,000

PROJECT STATEMENT

(On basis of appropriation)

Project	1993		1994		1995	
	Actual	Staff:	Estimated:	Staff:	Estimated	Staff
	Amount	Years	Amount	Years	Increase	Amount
Research, Analysis & Technical	:	:	:	:	:	:
Assistance.....	\$8,397,356	109	\$11,068,000	103	+7,335,000	\$18,403,000: 100
Unobligated Balance.....	140,644	---	---	---	---	---
Total,	:	:	:	:	:	:
Appropriation..	8,538,000	109	11,068,000	103	+7,335,000	18,403,000: 100

EXPLANATION OF PROGRAM

Overview of Program Development. General authority for nutrition research and education comes from the mission mandated by Congress when the Department was established in 1862. The Organic Act of 1862 called for an institution, the "general design and duties of which shall be to acquire and diffuse among the people of the United States useful information on subjects connected to agriculture and rural development." Nutrition was subsequently specified as one such subject.

Early studies on food and nutrition were begun at the end of the last century by Dr. W.O. Atwater, the first director of USDA's Office of Experiment Stations. These small scale studies were aimed at helping the working class achieve good diets at low cost. The first food consumption survey of national scope was the "Consumer Purchase Study of 1936-37" conducted jointly by USDA and the U.S. Department of Labor. This study indicated that one-third of the nation's families had diets rated poor by nutrition standards. These findings added impetus to efforts to enrich flour and bread with iron and three B vitamins and to initiate school lunch programs and more vigorous nutrition education efforts.

The types of food eaten and the dietary status of the population have been measured subsequently through the decennial Nationwide Food Consumption Surveys (NFCS). The last NFCS was conducted in 1987-88. The results of these studies reflect changes over the years in the distribution and storage (refrigeration) of products, in the availability of convenience foods (mixes and ready-made products), in technology (more commercially frozen foods and new packaging), and in incomes and lifestyles (more working women). Having available up-to-date food consumption data is essential to understanding both the dietary status of the population and the safety of the food supply.

The Research and Marketing Act of 1946 explicitly authorized research into problems of human nutrition and of the nutritive value of agriculture commodities. The role of USDA in conducting research in the fields of human nutrition, food consumption patterns, nutritive value of foods, and nutrition education activities was affirmed in the Food and Agriculture Act of 1977. Title XIV of this Act, "The National Agricultural Research, Extension, and Teaching Policy Act of 1977," established USDA as the lead agency in the Federal Government for research, extension, and teaching in the food and agricultural sciences. Further, it directed that research into food and human nutrition be established as a separate and distinct mission of the Department. With this legislation, Congress supported USDA's traditional emphasis on the nutritional needs of normal, healthy individuals rather than the needs of individuals requiring clinical or therapeutic dietary support, which is the responsibility of the U.S. Department of Health and Human Services. This mission was reaffirmed in the Agriculture and Food Act of 1981 and the Food Security Act of 1985.

The National Nutrition Monitoring and Related Research Act of 1990 directed better coordination of nutrition monitoring government-wide and an expansion of activities in food consumption assessment, food composition research, and dietary guidance in order to strengthen national nutrition monitoring and foster nutrition education.

HNIS has been designated to play a leadership role in providing the policy basis for Federal dietary guidance to the public for several years in conference reports accompanying the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bills.

HNIS was established on October 1, 1981, by the Secretary's Memorandum No. 1000-1 issued pursuant to Reorganization Plan No. 1 of 1953 (7 U.S.C. 2201). The functions of this agency were formerly carried out in the Agricultural Research Service. Currently HNIS conducts the activities authorized under "Research Analysis and Technical Assistance" in sections 1451-1453 and 1589 of Public Law 99-198 (7 U.S.C. 3173 note and 3178a).

Streamlining the Agency.

Consistent with the President's directive dated September 11, 1993, recommendations of the Vice President's National Performance Review, and the Secretary's reorganization plan, the Human Nutrition Information service is developing plans to streamline its operations, increase efficiency, and minimize bureaucracy. Specifically,

-- The Human Nutrition Information Service will be restructured to emphasize

nutrition research and education, creating the Nutrition Research and Education Service (NRES).

- NRES will employ a "lead agency" concept, with its larger sister agency, the Food and Consumer Service (FCS), providing management and administrative services for both agencies.
- Personnel requirements will be reduced through reorganization and improvements in efficiency. By the end of FY 1995, NRES will reduce its staffing level from 110 to 100, a 9 percent reduction, and thereafter to 97 in 1996, 95 in 1997, and 93 in both 1998 and 1999.

Agency Objectives. It is USDA policy to "promote optimal human health and well-being through improved nutrition," Departmental Regulation 1020-4. HNIS implements this policy through three activities, including:

1) Nutrition Education.

HNIS will continue its program in nutrition education designed to:

- o Help establish the standards for Healthy Eating through activities such as the review of the Dietary Guidelines for Americans and development and maintenance of the research base for the Food Guide Pyramid.
- o Develop and test materials and education strategies that help consumers improve their diet. This includes conducting research on food selection guidance and food preparation procedures and recipe modification, basic communication and educational research as well as the promotion and evaluation of educational materials and strategies. Current efforts focus on promoting Healthy Eating by promoting the Food Guide Pyramid and developing guidance for adapting the Pyramid for special uses. HNIS's budget for Nutrition Education remains unchanged from FY 1994 at \$0.9 million.

2) Nutrition Monitoring.

- o Through the National Nutrition Monitoring and Related Research Program (NNMRP), USDA proposes to strengthen nutrition monitoring by increasing efforts to measure the food and nutrition behavior of the general population and specific population subgroups, in order to better understand and target problem areas in food assistance, nutrition education, and food safety.
- o The Continuing Survey of Food Intakes by Individuals (CSFII) 1994-1996 is the third in a series of CSFIIs conducted since 1985. A telephone follow-up survey, the Diet and Health Knowledge Survey (DHKS), in CSFII 1989-91 is conducted concurrently with the CSFII. The surveys' target population consists of noninstitutionalized individuals in the 50 States and Washington, D.C. The number of CSFII respondents is expected to be approximately 16,000 over 3 years. The number of DHKS respondents is expected to be approximately 4,500 over 3 years. About one quarter of the sample will consist of persons from low-income households.
- o CSFII 1994-1996 is designed to obtain 2 independent days of food intake data from designated individuals in the household, in addition to sociodemographic, and diet and health-related questions. Data are used by policy-makers in formulating goals and policies for food and nutrition intervention programs. To improve the ability of these surveys to address the varied needs of Federal users, HNIS also created a Continuing Survey Users Group with representatives from several agencies that are major users of food consumption data.

- o HNIS has requested additional funds in its FY 1995 budget for two proposals supporting the Administration's initiative on pesticides and food safety. These proposals are for the development and implementation of a food intake survey of infants and children in 1996 that will supplement the CSFII 1994-96 and for research to link intake data from the CSFII 1989-91 and the National Health and Nutrition Education Survey (NHANES) III, Phase I. These proposals will provide the Environmental Protection Agency with increased data on infants and children in the short term. HNIS's budget for Nutrition Monitoring is \$16.6 million for FY 1995, an increase of \$7.8 million from FY 1994.

3) Nutrition Research

HNIS will continue its program in nutrition research designed to:

- o Develop USDA food plans including the Thrifty Food Plan which is the basis for Food Stamp allotments and to study the effect of economic factors on food sufficiency and dietary status.
- o Assess how well Americans are following the recommendations for Healthy Eating and assess the factors that influence their dietary status. This is done through assessment of the trends in the nutrient content of the U.S. food supply since the beginning of the century and through analysis of individual intake data from the National Nutrition Monitoring and Related Research Program as well as other sources and includes the development and testing of analytical methods. HNIS's budget for Nutrition Research is \$0.9 million, a decrease of \$0.4 million from FY 1994.

JUSTIFICATION OF INCREASES AND DECREASES

Mission: The Human Nutrition Information Service (HNIS) promotes the nutritional well-being of Americans by developing nutrition policy for the nation, educating American on that policy, monitoring the food consumption of the population and maintaining the Nutrient Data Bank. To accomplish this, HNIS:

- o Develops and promotes Dietary Guidelines for Americans through:
 - Nutrition education curriculum and materials
 - The Food Guide Pyramid
 - o Conducts applied research in food and nutrition:
 - What Americans buy and eat
 - Nutrient content of foods
 - o Provides leadership in National Nutrition Monitoring and Related Research
 - o Disseminates research findings used to make informed policies:
 - Food labeling, food safety and pesticide residue regulation
 - Food formulation, production, marketing
 - Development of nutrition education programs
- (1) A net increase of \$7,335,000 for research and analysis, and other expenses consisting of:
- (a) A decrease of \$180,000 and 3 staff years for a reduction in Federal employment costs.

Need for Change. In support of the Secretary's streamlining efforts and the President's Executive Order mandating a reduction in Federal employment, HNIS is reducing employment from the FY 1993 base by 9 percent.

Nature of Change. To achieve the reduction, HNIS will streamline its operations. The total reduction in personnel costs amounts to \$180,000.

(b) A decrease of \$309,000 for administrative efficiency.

Need for Change. In support of the Secretary's streamlining efforts and the President's Executive Order to reduce overhead-type outlays from the FY 1993 baseline, budget authority is reduced by \$309,000.

Nature of Change. In order to achieve these savings, HNIS will reduce discretionary expenses by \$309,000 in FY 1995, in areas such as training, travel and other controllable administrative costs.

(c) An increase of \$62,000 for the Fiscal Year 1995 pay raise.

(d) A net increase of \$7,562,000 for the Children's Food Intakes and Pesticide Data Initiative.

Need for Change. More specifically, the 1993 National Academy of Sciences Report on Pesticide Residues in the Diets of Children highlighted the need for HNIS food surveys to provide additional data on the food intakes of children in order to meet the requirements of the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) in ensuring the safety of the food supply. The Academy concluded that food consumption patterns for infants and children differ markedly from those of adults, and that the current regulatory system does not specifically consider infants and children. Food intakes from larger samples of children should be collected in order for EPA and FDA to establish adequate safety thresholds. In response to the Academy's recommendation HNIS will conduct (1) a special survey that builds on and supplements the data gathered in the Continuing Survey of Food Intakes by Individuals 1994-1996 (CSFII) and (2) merges the CSFII and the National Health and Nutrition Education Survey (NHANES) databases, if possible, to more completely address the short term data needs of EPA.

Nature of Change. Funds requested will be utilized to develop a special survey of children's food intakes based on EPA's preferred sample distribution. The survey will entail contracts to work in even greater cooperation with EPA, FDA, and the health and scientific community to implement recommendations contained in the Academy's report.

(e) A net increase of \$200,000 to maintain food composition research and management of the National Nutrient Databank System (NDBS).

Need for change. To maintain food composition research and management of the NDBS and other associated nutrient data bases (survey nutrient database, and Child Nutrition Program Nutrient Database. The NDBS represents the critical link, persons nutritive values necessary to translate individual food intake and food production into information useful in the evaluation of the impact of USDA programs and policies on the nutritional status of the U.S. population, especially high risk groups such as children and low-income persons. The NDBS is used (1) to store and summarize food composition data (Handbook No. 8); (2) to provide nutritive values to the food intake data collected in USDA and DHHS surveys in the National Nutrition Monitoring and Related Research Program; (3) to provide nutritive values for the development of nutrient standard based meals served in the school lunch program and; (4) to provide nutritive values for the food industry to label meat products according to new labeling regulations.

Recently, the General Accounting Office (GAO) released a study highlighting the significance of the National Nutrient Databank System and calling for greater quality control regarding the data. HNIS is moving forward to implement these changes. New funding will be directed to quality improvements for data management.

Nature of Change. Currently, the NDBS contains data on 5,300 food items. Annual supplements, which update and expand nutrient data, are compiled based on research, food industry sources and the scientific literature. These supplements are published and electronically available on the USDA Bulletin Board for use by USDA, other federal agencies, the food industry, and other researchers. The Bulletin Board telephone number is 301-436-5078. No additional staff years will be needed to support this initiative.

Human Nutrition Information Service
GEOGRAPHIC BREAKDOWN OF OBLIGATIONS AND STAFF-YEARS
1993 and Estimated 1994 and 1995

	1993		1994		1995	
	-----		-----		-----	
	Staff		Staff		Staff	
	Amount	Years	Amount	Years	Amount	Years
	-----	-----	-----	-----	-----	-----
Maryland.....	\$8,397,356	109	\$11,068,000	103	\$18,403,000	100
Unobligated						
balance.....	140,644	--	---	--	---	--
	-----		-----		-----	
Total, Available						
or Estimate	8,538,000	109	11,068,000	103	18,403,000	100

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HUMAN NUTRITION INFORMATION SERVICE

STATUS OF PROGRAM

The Human Nutrition Information Service (HNIS) is responsible for conducting applied research in food and nutrition--what foods Americans buy and eat, what nutrients are in the foods we eat, and how we can make informed food choices. HNIS research is used by policymakers to formulate research-based policies for nutrition and food intervention programs; consumer education including the Dietary Guidelines for Americans, which are the basis of Federal dietary guidance policy for the public; food fortification; food safety; and regulatory activities.

Current Activities carried out by HNIS include:

1. Food Intake Research. Plan, manage, and report results of nationwide surveys of food consumption and dietary practices and behaviors by households and individuals, including the Continuing Survey of Food Intakes by Individuals, and the Diet and Health Knowledge Survey. Develop, carry out, and report a program of research to improve food-consumption survey concepts and methods consistent with provisions of the National Nutrition Monitoring and Related Research Act of 1990.
2. Food Composition Research and the Food and Nutrient Data Bases. Direct research and gather data to determine the nutrient content of foods available to Americans, develop standard reference tables on the nutrient composition of foods, and manage the National Nutrient Data Bank.
3. Applied Research on the Dietary Status of the U.S. Population. Provide research-based information for decision-making by Government policymakers, educators, and health professionals aimed at improving the nutritional quality of the American diet.
4. Nutrition Education Research. Develop dietary guidance concepts and techniques to help the American public make informed food choices.
5. Policy Coordination. Serve as lead USDA agency for the National Nutrition Monitoring and Related Research Program, for the development of the Dietary Guidelines for Americans--the basis for Federal dietary guidance policy, and for a number of Federal and Federal/private nutrition education activities such as the National Cholesterol Education Program. These activities are coordinated with the U.S. Department of Health and Human Services (DHHS) and other agencies.

Food Intake Research

A fixed-price contract for the 1994-96 Continuing Survey of Food Intakes by Individuals (CSFII) and the Diet and Health Knowledge Survey (DHKS) was awarded. CSFII/DHKS 1994-96 was developed in direct response to Congress' request that HNIS improve methodology and contracting procedures and enhance survey data quality. Emphasis has been placed on improved survey management, high response rates, extensive quality controls and reduced respondent burden.

Data from these surveys have a major effect on nutrition policy, the design of nutrition programs, food fortification policy and food safety policy. Over the three-year period, a nationally representative sample of 15,000 individuals (with a subset sample of 45 percent low income) will be asked, through in-person interviews, to recall their food intakes on two nonconsecutive days and socioeconomic and health-related information. About two weeks after the CSFII, through telephone follow-up, 4,000 individuals are asked to answer DHKS questions about knowledge and attitudes toward dietary guidance and health. A pilot study to test data collection methods and survey operations was successfully completed in Spring 1993 and the actual survey began in January 1994.

CSFII/DHKS 1989-91 has been completed. This survey was designed to obtain 3-day food intake data from 15,000 individuals in addition to sociodemographic data and general questions on respondents' diet and health. The DHKS 1989-91 is significant in that it represents the first time that a nationwide survey was used to study the relationship between individuals' actual dietary intakes and their attitudes about dietary behavior. Data tapes providing results from the 1989 and 1990 CSFII/DHKS have been made available for public distribution through the National Technical Information Service.

Food Composition Research and the Food and Nutrient Data Bases

HNIS's National Data Bank and Agriculture Handbook 8 are the world's principal sources of food composition data. The Handbook and the related USDA databases are essential to a wide spectrum of researchers, teachers, federal agencies and international organizations. With nutrient analysis costing about \$2,000 per sample and it being desirable to base data on 6 or more samples, it is too expensive for HNIS or any other entity to maintain ideal data on all foods. However, HNIS requires stringent quality assurance standards for the nutrient analyses under contract. Potential contractors are screened according to performance, including their written proposal as well as by analyses of reference materials. HNIS contracts have focused on monitoring nutrients in foods that are major contributors of those nutrients. Quality assurance of data submitted by outside sources is, however, being strengthened and will require more documentation. A new and improved Nutrient Data Bank System is currently being developed to meet future needs and will address issues of concern. This new system will address the needs of the varied users and help assure improved quality of nutrient data.

Updated information on the composition of pork products was released in a revision to Agriculture Handbook Section Number 8-10. In addition, the 1992 Supplement to the Handbook was published. These Handbook revisions are available through the HNIS electronic Nutrient Databank Bulletin Board and upon requests from data users in the government, food industry and academia.

Extramural contracts were used for monitoring nutrient composition data. These included lipid components including fat, fatty acids, cholesterol, and plant sterols in selected foods; and total dietary fiber in selected foods. Key foods were analyzed for vitamins, minerals, and proximates (protein, fat, carbohydrate, moisture). Data obtained through these activities have been added to the National Nutrient Data Bank and form the basis for supplements to the Handbook.

Work began on a Nutrient Data Base for Child Nutrition Programs which will be used in a demonstration project for nutrient standard menu planning in the National School Lunch Programs beginning in 1994. Planning is underway for a redesign of the Nutrient Data Bank computer system to enhance database management, better utilize current electronic technology and to expand the level of detail recorded about food composition measurements.

HNIS, with the cooperation of the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), is refining its Food Grouping System to translate survey data on foods consumed into raw agricultural commodities that can be linked with pesticide residue data. The purpose of the Food Grouping System is to increase the usefulness of food consumption data collected in national surveys. Information on food is collected the way people eat it--as separate items such as a piece of chicken, or as mixtures such as pizza. Before the Food Grouping System, pizza would have been totally classified as a grain product and we would not know how much of the food was actually cheese, tomatoes, or flour. The Food Grouping System allows us to translate the information on consumption of pizza and other mixtures into data on consumption of the specific ingredients, or even further to the level of raw agricultural commodities. The Food Grouping System will provide intake data on food and commodities for EPA and other organizations to determine potential residue exposures for the total population and population subgroups, thereby enhancing risk assessments. Contract

acquisition by the General Services Administration's Federal Office System Support Division is in progress with award anticipated in 1994.

Research on the Dietary Status of the U.S. Population

The U.S. Food Supply Series, a historical series that dates from 1909 was updated to 1991. This data is the only source of information which provides a consistent measure of foods and nutrients available for consumption since the beginning of the century. A contract with Fu Associates was signed to provide production of the primary report entitled "Nutrient Content of the U.S. Food Supply" in 1994. This publication has a wide audience which includes nutrition and public health professionals, epidemiologists, public policy makers, agricultural economists, food industry and marketing analysts, among others. This publication will present the most up-to-date information available. In addition, food supply data are regularly provided for inclusion in other publications, e.g., Agricultural Statistics, Statistical Abstract of the United States, and the Bureau of the Census' Historical Abstracts. Several articles and speeches report on specific aspects of the food supply data.

Plans were made for two major research efforts, one, to develop the research base for an overall measure of diet quality for the U.S. population, and population subgroups (a "Healthy Eating Index") and two, to identify knowledge, attitude and behavior related questions primarily from the Diet and Health Knowledge Survey (DHKS) that are accurate "Indicators of Healthy Eating" defined as following current dietary recommendations. In preparation for the "Indicators of Healthy Eating" project, a contract was signed with Market Research Corporation of America (MRCS) to identify DHKS type questions which estimate "Healthy Eating". To the same purpose, a grant was awarded to the Cooperative Extension System (CES) to focus on questionnaire development to assess the effect of nutrition education programs.

The cost of four USDA family food plans--thrifty, low-cost, moderate-cost, and liberal--was released monthly in FY 1993. A historical report on the Thrifty Food Plan development was written. This report serves as an excellent overview on food plan development and methodology for food plan staff or individuals interested in the history of food assistance programs.

Nutrition Education Research and Information

The Food Guide Pyramid, developed to help people follow the Dietary Guidelines for Americans, has been used extensively by public and private organizations as a tool for nutrition education and in conjunction with other nutrition education materials. For example, the Food Guide Pyramid has been used by professional associations such as the American Dietetic Association, the Society for Nutrition Education and other health and education groups. It has been used in articles, consumer brochures, food labels, advertising, posters, curricula for school age children, video and boxed games, and much more.

HNIS staff has written or given many articles and speeches explaining the research base for the Food Guide and how to use it for professional audiences. Materials have also been developed for consumers. For example, a new set of eight bulletins on the Dietary Guidelines has been released. The set includes an overview and seven individual bulletins, each focusing on one guideline. Information on using the Food Guide Pyramid in menu planning, as well as practical suggestions and recipes, and food preparation tips are included. The two-color bulletins are designed to be readily reproduced to enhance their usefulness in a variety of nutrition education programs. Several other publications were released to present information on healthy eating to high-risk audiences: Making Healthy Food Choices for low literate adults; Food Facts for Older Adults; and Dietary Guidelines and Your Health, a teaching kit for health educators to use with students in junior and senior high schools. Development of materials that show professionals and consumers how to use the Food Guide Pyramid and the new nutrition label as tools

for healthy eating are nearing completion. The educational materials developed by HNIS are based on nutrition education research on the dietary status of Americans and the factors that influence dietary status.

HNIS provides leadership for an interagency working group that reviews all USDA and DHHS publications that present dietary guidance for the general public. The review process is intended to ensure that guidance conforms to the Dietary Guidelines for Americans and is consistent and supportive across USDA agencies and the Federal Government. The group is composed of representatives from ten USDA agencies that are involved in nutrition education. A similar group reviews dietary guidance materials within DHHS.

Policy Coordination

As the USDA lead agency for the National Nutrition Monitoring and Related Research Program, HNIS works with other agencies both inside and outside USDA to coordinate monitoring activities. HNIS, along with DHHS, provides Co-Executive Secretaries to the National Nutrition Monitoring Advisory Council. The Co-Executive Secretaries provide technical assistance and administrative service in the operation of the Council. HNIS provides liaison to the Executive Secretary for the Interagency Board on Nutrition Monitoring and Related Research (IBNMRR), which is cochaired by the USDA Assistant Secretary for Food and Consumer Services and the DHHS Assistant Secretary of Health. Through the activities of working groups of the IBNMRR, issues are being addressed on survey comparability, Federal and State information dissemination and exchange, and food composition. Implementation of the requirements defined in P.L. 101-445, the National Nutrition Monitoring and Related Research Act of 1990, is a major initiative within USDA in coordination with DHHS. As required by the law, USDA and DHHS have developed the Ten-Year Comprehensive Plan for Nutrition Monitoring and Related Research. The Plan lays out direction and activities in nutrition monitoring that the Federal government will take for the next decade.

HNIS is the lead for USDA, in coordination with DHHS, to contract with a scientific body to interpret available data and publish a report on the dietary, nutritional, and health-related status of the people of the United States. This scientific report is required by P.L. 101-445. HNIS further provides the USDA liaison to the National Cholesterol Education Campaign Coordinating Committee and the USDA member to the Working Group for the Year 2000 Nutrition Objectives, both of which are DHHS health promotion and disease prevention initiatives.

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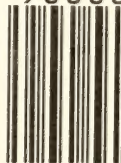
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